US3472001 (Prod: Penn Prevention - (CRS))

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:42:27

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US3472001
Form: Participant Creation
Data signed: (b) (4) **29 Mar 2021 15:32:10**
Generated On: 09 Jun 2021 17:42:27

Participant ID	US3472001

mRNA-1273-P301 Completion Guidelines

FDA-CBER-2022-1614-1778499

US3472001
Folder: Screening
Form: Visit Date
Data signed: (b) (4) **29 Mar 2021 15:32:11**
Generated On: 09 Jun 2021 17:42:27

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	31 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	SCRN

FDA-CBER-2022-1614-1778500

US3472001
Folder: Screening
Form: Demographics
Data signed: (b) (4) **29 Mar 2021 15:32:11**
Generated On: 09 Jun 2021 17:42:27

Date of Birth (MMM yyyy)	(b) (6) 1950
Age	70
Age Units	YEARS
Age (Derived)	70
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

FDA-CBER-2022-1614-1778501

US3472001
Folder: Screening
Form: Enrollment
Data signed: (b) (4) **29 Mar 2021 15:32:11**
Generated On: 09 Jun 2021 17:42:27

Date of Informed Consent *(dd MMM yyyy)*	31 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

FDA-CBER-2022-1614-1778502

US3472001
Folder: Screening
Form: Inclusion/Exclusion Criteria Summary
Data signed: (b) (4) **29 Mar 2021 15:32:11**
Generated On: 09 Jun 2021 17:42:27

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

FDA-CBER-2022-1614-1778503

US3472001
Folder: Screening
Form: Medical History Summary
Data signed: (b) (4) **29 Mar 2021 15:32:11**
Generated On: 09 Jun 2021 17:42:27

Were any significant conditions reported?	Yes ■ No ☐

FDA-CBER-2022-1614-1778504

US3472001
Folder: Screening
Form: Medical History (1)
Data signed: (b) (4) **29 Mar 2021 15:32:11**
Generated On: 09 Jun 2021 17:42:27

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

FDA-CBER-2022-1614-1778505

US3472001
Folder: Screening
Form: Medical History (2)
Data signed: (b) (4) **29 Mar 2021 15:32:11**
Generated On: 09 Jun 2021 17:42:27

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

FDA-CBER-2022-1614-1778506

US3472001
Folder: Screening
Form: Medical History (3)
Data signed: (b) (4) **29 Mar 2021 15:32:11**
Generated On: 09 Jun 2021 17:42:27

Condition	OSTEOARTHRITIS IN BOTH LOWER EXTREMITIES
Start date (dd MMM yyyy)	UN UNK 2005
Start date completely unknown	False
Condition ongoing at study entry	Yes ■ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-1778507

US3472001
Folder: Screening
Form: Medical History (4)
Data signed: (b) (4) **29 Mar 2021 15:32:11**
Generated On: 09 Jun 2021 17:42:27

Condition	WOLF PARKINSON WHITE SYNDROME
Start date (dd MMM yyyy)	UN UNK 2005
Start date completely unknown	False
Condition ongoing at study entry	Yes ■ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-1778508

US3472001
Folder: Screening
Form: Medical History (5)
Data signed: (b) (4) **29 Mar 2021 15:32:11**
Generated On: 09 Jun 2021 17:42:27

Condition	BENIGN RENAL CYST
Start date (dd MMM yyyy)	UN AUG 2012
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)	AUG 2012
Start Year (derived)	2012
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-1778509

US3472001
Folder: Screening
Form: Medical History (6)
Data signed: (b) (4) **29 Mar 2021 15:32:11**
Generated On: 09 Jun 2021 17:42:27

Condition	OBSTRUCTIVE SLEEP APNEA
Start date (dd MMM yyyy)	UN UNK 2012
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 2012
Start Year (derived)	2012
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-1778510

US3472001
Folder: Screening
Form: Medical History (7)
Data signed: (b) (4) **29 Mar 2021 15:32:11**
Generated On: 09 Jun 2021 17:42:27

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

FDA-CBER-2022-1614-1778511

US3472001
Folder: Screening
Form: Medical History (8)
Data signed: (b) (4) **29 Mar 2021 15:32:11**
Generated On: 09 Jun 2021 17:42:27

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

FDA-CBER-2022-1614-1778512

US3472001
Folder: Screening
Form: Medical History (9)
Data signed: (b) (4) **29 Mar 2021 15:32:11**
Generated On: 09 Jun 2021 17:42:27

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

FDA-CBER-2022-1614-1778513

US3472001
Folder: Screening
Form: Medical History (10)
Data signed: (b) (4) **29 Mar 2021 15:32:11**
Generated On: 09 Jun 2021 17:42:27

Condition	HYPERLIPIDEMIA
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-1778514

US3472001
Folder: Screening
Form: Medical History (11)
Data signed: (b) (4) **29 Mar 2021 15:32:11**
Generated On: 09 Jun 2021 17:42:27

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

FDA-CBER-2022-1614-1778515

US3472001
Folder: Screening
Form: Vital Signs
Data signed: (b) (4) **29 Mar 2021 15:32:11**
Generated On: 09 Jun 2021 17:42:27

Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	31 AUG 2020
Time of assessment *(00:00-23:59)*	8:18 (24 HR)
Vital Signs Date and Time (derived)	31 AUG 2020 8:18
Height *(xxx.x)*	63 in
Weight *(xxx.x)*	120.7 kg
BMI *(xxx.x)*	47.13665 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)	

FDA-CBER-2022-1614-1778516

US3472001
Folder: Screening
Form: Physical Examination
Data signed: (b) (4) **29 Mar 2021 15:32:11**
Generated On: 09 Jun 2021 17:42:27

Was the physical examination performed?	Yes ■ No ☐
Date of examination *(dd MMM yyyy)*	31 AUG 2020

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

FDA-CBER-2022-1614-1778517

US3472001
Folder: Screening
Form: Risk of Exposure
Data signed: (b) (4) **29 Mar 2021 15:32:11**
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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

FDA-CBER-2022-1614-1778518

US3472001
Folder: Screening
Form: Risk of Exposure
Data signed: (b) (4) **29 Mar 2021 15:32:11**
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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-2022-1614-1778519

US3472001
Folder: Visit 1 Day 1
Form: Visit Date
Data signed: (b) (4) **29 Mar 2021 15:32:11**
Generated On: 09 Jun 2021 17:42:27

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	31 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	VISIT1

FDA-CBER-2022-1614-1778520

US3472001
Folder: Visit 1 Day 1
Form: Randomization
Data signed: (b) (4) **29 Mar 2021 15:32:11**
Generated On: 09 Jun 2021 17:42:27

What was the date of randomization? *(dd MMM yyyy)*	31 AUG 2020
What was the participant's randomization number?	189047
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-2022-1614-1778521

US3472001
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Data signed: (b) (4) **29 Mar 2021 15:32:11**
Generated On: 09 Jun 2021 17:42:27

Height	ND - Not Done
Weight	ND - Not Done

FDA-CBER-2022-1614-1778522

US3472001
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Data signed: (b) (4) **29 Mar 2021 15:32:11**
Generated On: 09 Jun 2021 17:42:27

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)*	31 AUG 2020
Time of assessment *(00:00-23:59)*	8:18 (24 HR)
Vital Signs Date and Time (derived)	31 AUG 2020 8:18
Temperature *(xxx.x)*	37.2 C
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	87 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	80 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-1778523

US3472001
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Data signed: (b) (4) **29 Mar 2021 15:32:11**
Generated On: 09 Jun 2021 17:42:27

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)*	31 AUG 2020
Time of assessment *(00:00-23:59)*	11:50 (24 HR)
Vital Signs Date and Time (derived)	31 AUG 2020 11:50
Temperature *(xxx.x)*	36.2 C
Route of measurement	Oral ● Axillary ○ Other ○
If Other, specify	
Pulse *(xxx)*	85 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	106 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	65 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-1778524

US3472001
Folder: Visit 1 Day 1
Form: Physical Examination
Data signed: (b) (4) **29 Mar 2021 15:32:11**
Generated On: 09 Jun 2021 17:42:27

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-2022-1614-1778525

US3472001
Folder: Visit 1 Day 1
Form: Exposure
Data signed: (b) (4) **29 Mar 2021 15:32:11**
Generated On: 09 Jun 2021 17:42:27

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)*	31 AUG 2020
What was the treatment time? *(00:00-23:59)*	11:21 (24 HR)
Treatment Date and Time (derived)	31 AUG 2020 11:21
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-2022-1614-1778526

US3472001
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Data signed: (b) (4) **29 Mar 2021 15:32:11**
Generated On: 09 Jun 2021 17:42:27

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	31 AUG 2020
Collection time *(00:00-23:59)*	9:55 (24 HR)
Collection date and time (derived)	31 AUG 2020 9:55

FDA-CBER-2022-1614-1778527

US3472001
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab
Data signed: (b) (4) **29 Mar 2021 15:32:11**
Generated On: 09 Jun 2021 17:42:27

Collection date *(dd MMM yyyy)*			31 AUG 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	9:05	31 AUG 2020 9:05
Nasopharyngeal Swab 2	No		

FDA-CBER-2022-1614-1778528

US3472001
Folder: Visit 1 Day 1
Form: Continuing
Data signed: (b) (4) **29 Mar 2021 15:32:11**
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Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-1778529

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**	_____
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ☐
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	_____
To **PREVENT** pain or fever from occurring	_____
PC Time Stamp	_____
PC Open Date & Time	31 AUG 2020 11:41
PC Close Date & Time	31 AUG 2020 14:11

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	97.6 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■

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

PC Time Stamp	31 AUG 2020 21:23
PC Open Date & Time	31 AUG 2020 15:06
PC Close Date & Time	01 SEP 2020 11:59

US3472001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 17:42:27

TIMEPOINT	DAY 2

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ☒ No ☐
Please record your **TEMPERATURE in °F**	98.6 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ☒
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	01 SEP 2020 16:09
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3472001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:42:27

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**	98.1 °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 19:29
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

FDA-CBER-2022-1614-1778533

US3472001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:42:27

TIMEPOINT	DAY 4

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ☒ No ☐
Please record your **TEMPERATURE in °F**	97.4 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ☒
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	03 SEP 2020 23:20
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

FDA-CBER-2022-1614-1778534

US3472001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 17:42:27

TIMEPOINT	DAY 5

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.3 °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	05 SEP 2020 00:00
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3472001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:42:27

TIMEPOINT	DAY 6

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	97.7 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	05 SEP 2020 19:09
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3472001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 17:42:27

TIMEPOINT	DAY 7

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	97.7 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	06 SEP 2020 17:44
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3472001
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:42:27

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 ☐
Please record - **REDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site redness with the ruler provided.	
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ☐
Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site swelling/hardness with the ruler provided.	
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ☐ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	
PC Open Date & Time	31 AUG 2020 11:41
PC Close Date & Time	31 AUG 2020 14:11

FDA-CBER-2022-1614-1778538

US3472001
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:42:27

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	31 AUG 2020 21:24
PC Open Date & Time	31 AUG 2020 15:06
PC Close Date & Time	01 SEP 2020 11:59

FDA-CBER-2022-1614-1778539

US3472001
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:42:27

TIMEPOINT	DAY 2
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	01 SEP 2020 16:10
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

FDA-CBER-2022-1614-1778540

US3472001
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:42:27

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	02 SEP 2020 19:29
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

FDA-CBER-2022-1614-1778541

US3472001
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:42:27

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	03 SEP 2020 23:21
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3472001
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:42:27

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	05 SEP 2020 00:00
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

FDA-CBER-2022-1614-1778543

US3472001
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:42:27

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	05 SEP 2020 19:09
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

FDA-CBER-2022-1614-1778544

US3472001
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:42:27

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	06 SEP 2020 17:44
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

FDA-CBER-2022-1614-1778545

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 ☐

US3472001
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:42:27

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	31 AUG 2020 11:55
PC Open Date & Time	31 AUG 2020 11:41
PC Close Date & Time	31 AUG 2020 14:11

FDA-CBER-2022-1614-1778547

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 ☐

US3472001
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:42:27

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	01 SEP 2020 06:48
PC Open Date & Time	31 AUG 2020 15:06
PC Close Date & Time	01 SEP 2020 11:59

FDA-CBER-2022-1614-1778549

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 ■

US3472001
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:42:27

	Yes ☐
PC Time stamp	01 SEP 2020 16:10
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

FDA-CBER-2022-1614-1778551

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 ■

US3472001
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:42:27

	Yes
PC Time stamp	02 SEP 2020 19:30
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

FDA-CBER-2022-1614-1778553

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 ■

US3472001
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:42:27

	Yes ☐
PC Time stamp	03 SEP 2020 23:21
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

FDA-CBER-2022-1614-1778555

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 ■

US3472001
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:42:27

	Yes
PC Time stamp	05 SEP 2020 00:01
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

FDA-CBER-2022-1614-1778557

US3472001
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:42:27

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-2022-1614-1778558

US3472001
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:42:27

	Yes
PC Time stamp	05 SEP 2020 19:10
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

TIMEPOINT	DAY 7
HEADACHE	None ■ No interference with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
FATIGUE	None ■ No interference with activity ☐ Some interference with activity ☐ Significant; prevents daily activity ☐
MUSCLE ACHES ALL OVER BODY	None ■ No interference with activity ☐ Some interference with activity ☐ Significant; prevents daily activity ☐
JOINT ACHES IN SEVERAL JOINTS	None ■ No interference with activity ☐ Some interference with activity ☐ Significant; prevents daily activity ☐
NAUSEA/VOMITING	None ■ No interference with activity or 1-2 episodes/24 hours ☐ Some interference with activity or >2 episodes/24 hours ☐ Prevents daily activity, requires outpatient IV hydration ☐
CHILLS	None ■ No interference with activity ☐ Some interference with activity not requiring medical attention ☐ Prevents daily activity and requires medical attention ☐
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■

US3472001
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:42:27

	Yes
PC Time stamp	06 SEP 2020 17:45
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

FDA-CBER-2022-1614-1778561

US3472001
Folder: Safety Call Day 8 (1)
Form: Safety Call
Data signed: (b) (4) **29 Mar 2021 15:32:11**
Generated On: 09 Jun 2021 17:42:27

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	7 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-2022-1614-1778562

US3472001
Folder: Safety Call Day 8 (1)
Form: Continuing
Data signed: (b) (4) **29 Mar 2021 15:32:11**
Generated On: 09 Jun 2021 17:42:27

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

FDA-CBER-2022-1614-1778563

US3472001
Folder: Safety Call Day 15 (1)
Form: Safety Call
Data signed: (b) (4) **29 Mar 2021 15:32:10**
Generated On: 09 Jun 2021 17:42:27

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	14 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-2022-1614-1778564

US3472001
Folder: Safety Call Day 15 (1)
Form: Continuing
Data signed: (b) (4) **29 Mar 2021 15:32:10**
Generated On: 09 Jun 2021 17:42:27

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

FDA-CBER-2022-1614-1778565

US3472001
Folder: Safety Call Day 22 (1)
Form: Safety Call
Data signed: (b) (4) **29 Mar 2021 15:32:10**
Generated On: 09 Jun 2021 17:42:27

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	21 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-2022-1614-1778566

US3472001
Folder: Safety Call Day 22 (1)
Form: Continuing
Data signed: (b) (4) **29 Mar 2021 15:32:10**
Generated On: 09 Jun 2021 17:42:27

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

FDA-CBER-2022-1614-1778567

US3472001
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Data signed: (b) (4) **29 Mar 2021 15:32:11**
Generated On: 09 Jun 2021 17:42:27

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	01 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	VISIT2

FDA-CBER-2022-1614-1778568

US3472001
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Data signed: (b) (4) **29 Mar 2021 15:32:11**
Generated On: 09 Jun 2021 17:42:27

Timepoint	Pre-Dose ■ Post-Dose ☐
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	01 OCT 2020
Time of assessment *(00:00-23:59)*	12:52 (24 HR)
Vital Signs Date and Time (derived)	01 OCT 2020 12:52
Temperature *(xxx.x)*	36.7 C
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	78 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	80 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-1778569

US3472001
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Data signed: (b) (4) **29 Mar 2021 15:32:11**
Generated On: 09 Jun 2021 17:42:27

Timepoint	Pre-Dose ☐ Post-Dose ■
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	01 OCT 2020
Time of assessment *(00:00-23:59)*	14:10 (24 HR)
Vital Signs Date and Time (derived)	01 OCT 2020 14:10
Temperature *(xxx.x)*	36.9 C
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	64 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	87 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-1778570

US3472001
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Data signed: (b) (4) **29 Mar 2021 15:32:11**
Generated On: 09 Jun 2021 17:42:27

Was the physical examination performed?	Yes ■ No ☐
Date of examination *(dd MMM yyyy)*	01 OCT 2020

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

FDA-CBER-2022-1614-1778571

US3472001
Folder: Visit 2 Day 29 (1)
Form: Exposure
Data signed: (b) (4) **29 Mar 2021 15:32:11**
Generated On: 09 Jun 2021 17:42:27

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)*	01 OCT 2020
What was the treatment time? *(00:00-23:59)*	13:38 (24 HR)
Treatment Date and Time (derived)	01 OCT 2020 13:38
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-2022-1614-1778572

US3472001
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **29 Mar 2021 15:32:11**
Generated On: 09 Jun 2021 17:42:27

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	01 OCT 2020
Collection time *(00:00-23:59)*	13:20 (24 HR)
Collection date and time (derived)	01 OCT 2020 13:20

FDA-CBER-2022-1614-1778573

US3472001
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab
Data signed: (b) (4) **29 Mar 2021 15:32:11**
Generated On: 09 Jun 2021 17:42:27

Collection date *(dd MMM yyyy)*			01 OCT 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:00	01 OCT 2020 13:00
Nasopharyngeal Swab 2	No		

FDA-CBER-2022-1614-1778574

US3472001
Folder: Visit 2 Day 29 (1)
Form: Continuing
Data signed: (b) (4) **29 Mar 2021 15:32:11**
Generated On: 09 Jun 2021 17:42:27

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

FDA-CBER-2022-1614-1778575

US3472001
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 17:42:27

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**	98.4 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■

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

PC Time Stamp	01 OCT 2020 14:10
PC Open Date & Time	01 OCT 2020 13:58
PC Close Date & Time	01 OCT 2020 16:28

FDA-CBER-2022-1614-1778576

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	97.7 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	01 OCT 2020 22:34
PC Open Date & Time	01 OCT 2020 17:23
PC Close Date & Time	02 OCT 2020 11:59

US3472001
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 17:42:27

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**	98.3 °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	02 OCT 2020 18:15
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

FDA-CBER-2022-1614-1778578

US3472001
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:42:27

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**	98.4 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ☒
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	03 OCT 2020 19:11
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3472001
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:42:27

TIMEPOINT	DAY 4

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.1 °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	04 OCT 2020 19:47
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3472001
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 17:42:27

TIMEPOINT	DAY 5

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	97.6 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	05 OCT 2020 19:32
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3472001
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:42:27

TIMEPOINT	DAY 6

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.3 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	06 OCT 2020 20:32
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

US3472001
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 17:42:27

TIMEPOINT	DAY 7

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.4 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	07 OCT 2020 20:27
PC Open Date & Time	07 OCT 2020 12:00
PC Close Date & Time	08 OCT 2020 11:59

US3472001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:42:27

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	01 OCT 2020 14:11
PC Open Date & Time	01 OCT 2020 13:58
PC Close Date & Time	01 OCT 2020 16:28

FDA-CBER-2022-1614-1778584

US3472001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:42:27

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	01 OCT 2020 22:34
PC Open Date & Time	01 OCT 2020 17:23
PC Close Date & Time	02 OCT 2020 11:59

US3472001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:42:27

TIMEPOINT	DAY 2
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	02 OCT 2020 18:15
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

FDA-CBER-2022-1614-1778586

US3472001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:42:27

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	03 OCT 2020 19:11
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

FDA-CBER-2022-1614-1778587

US3472001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:42:27

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	04 OCT 2020 19:47
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

FDA-CBER-2022-1614-1778588

US3472001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:42:27

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	05 OCT 2020 19:32
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

FDA-CBER-2022-1614-1778589

US3472001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:42:27

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	06 OCT 2020 20:32
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

FDA-CBER-2022-1614-1778590

US3472001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:42:27

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	07 OCT 2020 20:27
PC Open Date & Time	07 OCT 2020 12:00
PC Close Date & Time	08 OCT 2020 11:59

FDA-CBER-2022-1614-1778591

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 ☐

US3472001
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:42:27

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	01 OCT 2020 14:11
PC Open Date & Time	01 OCT 2020 13:58
PC Close Date & Time	01 OCT 2020 16:28

FDA-CBER-2022-1614-1778593

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 ☐

US3472001
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:42:27

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	01 OCT 2020 22:35
PC Open Date & Time	01 OCT 2020 17:23
PC Close Date & Time	02 OCT 2020 11:59

FDA-CBER-2022-1614-1778595

US3472001
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:42:27

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-2022-1614-1778596

US3472001
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:42:27

	Yes
PC Time stamp	02 OCT 2020 18:16
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

FDA-CBER-2022-1614-1778597

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 ■

US3472001
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:42:27

	Yes
PC Time stamp	03 OCT 2020 19:11
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

FDA-CBER-2022-1614-1778599

US3472001
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:42:27

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-2022-1614-1778600

US3472001
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:42:27

	Yes ☐
PC Time stamp	04 OCT 2020 19:48
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

FDA-CBER-2022-1614-1778601

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 ■

US3472001
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:42:27

	Yes
PC Time stamp	05 OCT 2020 19:33
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

FDA-CBER-2022-1614-1778603

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 ■

US3472001
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:42:27

	Yes ☐
PC Time stamp	06 OCT 2020 20:32
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

FDA-CBER-2022-1614-1778605

US3472001
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:42:27

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-2022-1614-1778606

US3472001
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:42:27

	Yes ☐
PC Time stamp	07 OCT 2020 20:27
PC Open Date & Time	07 OCT 2020 12:00
PC Close Date & Time	08 OCT 2020 11:59

FDA-CBER-2022-1614-1778607

US3472001
Folder: Safety Call Day 36 (1)
Form: Safety Call
Data signed: (b) (4) **29 Mar 2021 15:32:10**
Generated On: 09 Jun 2021 17:42:27

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	8 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-2022-1614-1778608

US3472001
Folder: Safety Call Day 36 (1)
Form: Continuing
Data signed: (b) (4) **29 Mar 2021 15:32:10**
Generated On: 09 Jun 2021 17:42:27

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

FDA-CBER-2022-1614-1778609

US3472001
Folder: Safety Call Day 43 (1)
Form: Safety Call
Data signed: (b) (4) **29 Mar 2021 15:32:10**
Generated On: 09 Jun 2021 17:42:27

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	15 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-2022-1614-1778610

US3472001
Folder: Safety Call Day 43 (1)
Form: Continuing
Data signed: (b) (4) **29 Mar 2021 15:32:10**
Generated On: 09 Jun 2021 17:42:27

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

FDA-CBER-2022-1614-1778611

US3472001
Folder: Safety Call Day 50 (1)
Form: Safety Call
Data signed: (b) (4) **29 Mar 2021 15:32:11**
Generated On: 09 Jun 2021 17:42:27

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

US3472001
Folder: Safety Call Day 50 (1)
Form: Continuing
Data signed: (b) (4) **29 Mar 2021 15:32:11**
Generated On: 09 Jun 2021 17:42:27

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

FDA-CBER-2022-1614-1778613

US3472001
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Data signed: (b) (4) **29 Mar 2021 15:32:11**
Generated On: 09 Jun 2021 17:42:27

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	26 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	VISIT3

FDA-CBER-2022-1614-1778614

US3472001
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Data signed: (b) (4) **29 Mar 2021 15:32:11**
Generated On: 09 Jun 2021 17:42:27

Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	26 OCT 2020
Time of assessment *(00:00-23:59)*	08:11 (24 HR)
Vital Signs Date and Time (derived)	26 OCT 2020 08:11
Temperature *(xxx.x)*	36.2 C
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	71 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	72 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

FDA-CBER-2022-1614-1778615

US3472001
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Data signed: (b) (4) **29 Mar 2021 15:32:11**
Generated On: 09 Jun 2021 17:42:27

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-2022-1614-1778616

US3472001
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **29 Mar 2021 15:32:11**
Generated On: 09 Jun 2021 17:42:27

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	26 OCT 2020
Collection time *(00:00-23:59)*	09:35 (24 HR)
Collection date and time (derived)	26 OCT 2020 09:35

FDA-CBER-2022-1614-1778617

US3472001
Folder: Visit 3 Day 57 (1)
Form: Continuing
Data signed: (b) (4) **29 Mar 2021 15:32:11**
Generated On: 09 Jun 2021 17:42:27

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

FDA-CBER-2022-1614-1778618

US3472001
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:27

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	31 OCT 2020 00:16:52
Patient Cloud Open Date & Time	31 OCT 2020 00:01
Patient Cloud Close Date & Time	04 NOV 2020 23:59

FDA-CBER-2022-1614-1778619

US3472001
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:27

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	07 NOV 2020 01:35:52
Patient Cloud Open Date & Time	07 NOV 2020 00:01
Patient Cloud Close Date & Time	11 NOV 2020 23:59

FDA-CBER-2022-1614-1778620

US3472001
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:27

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	14 NOV 2020 00:19:19
Patient Cloud Open Date & Time	14 NOV 2020 00:01
Patient Cloud Close Date & Time	18 NOV 2020 23:59

FDA-CBER-2022-1614-1778621

US3472001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:27

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 NOV 2020 19:44:28
Patient Cloud Open Date & Time	18 NOV 2020 00:01
Patient Cloud Close Date & Time	22 NOV 2020 23:59

US3472001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:27

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	25 NOV 2020 00:02:34
Patient Cloud Open Date & Time	25 NOV 2020 00:01
Patient Cloud Close Date & Time	29 NOV 2020 23:59

FDA-CBER-2022-1614-1778623

US3472001
Folder: Cosmetic Injections and Dermal Fillers
Form: Cosmetic Injection_ Dermal Filler eDiary
Generated On: 09 Jun 2021 17:42:27

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

FDA-CBER-2022-1614-1778624

US3472001
Folder: Safety Call Day 85 (1)
Form: Safety Call
Data signed: (b) (4) **29 Mar 2021 15:32:11**
Generated On: 09 Jun 2021 17:42:27

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	23 NOV 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments *If Contact Not Made, please provide Comments*	

FDA-CBER-2022-1614-1778625

US3472001
Folder: Safety Call Day 85 (1)
Form: Continuing
Data signed: (b) (4) **29 Mar 2021 15:32:11**
Generated On: 09 Jun 2021 17:42:27

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

FDA-CBER-2022-1614-1778626

US3472001
Folder: Safety Call Day 119 (1)
Form: Safety Call
Data signed: (b) (4) **29 Mar 2021 15:32:10**
Generated On: 09 Jun 2021 17:42:27

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*	THIS PPT PASSED AWAY 27NOV2020

FDA-CBER-2022-1614-1778627

US3472001
Folder: Safety Call Day 119 (1)
Form: Continuing
Data signed: (b) (4) **29 Mar 2021 15:32:10**
Generated On: 09 Jun 2021 17:42:27

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

FDA-CBER-2022-1614-1778628

US3472001
Folder: Covid-19 Assessment (1)
Form: COVID-19 Contact
Generated On: 09 Jun 2021 17:42:27

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	
Type of Contact	Clinic Visit - Scheduled ☐ Clinical Visit - Unscheduled ☐ Safety Call ☐ Convalescent Tele-visit ☐
Has the subject reported symptoms of SARS-COV-2?	Yes ☐ No ☐

FDA-CBER-2022-1614-1778629

US3472001
Folder: Covid-19 Assessment (1)
Form: Generate Next COVID-19 Assessment
Generated On: 09 Jun 2021 17:42:27

Generate Next COVID-19 Assessment	Yes ☐ No ☐

FDA-CBER-2022-1614-1778630

US3472001
Folder: Adverse Events
Form: Adverse Events Summary
Data signed: (b) (4) **29 Mar 2021 15:32:10**
Generated On: 09 Jun 2021 17:42:27

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

If Yes, enter details on the Adverse Events form.

FDA-CBER-2022-1614-1778631

US3472001
Folder: Adverse Events
Form: Adverse Events (1)
Data signed: (b) (4) **29 Mar 2021 15:32:10**
Generated On: 09 Jun 2021 17:42:27

AEID	
Adverse event	POSITIVE HEPATITIS C ANTIBODY
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)*	29 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)*	
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)	

US3472001
Folder: Adverse Events
Form: Adverse Events (2)
Data signed: (b) (4) **29 Mar 2021 15:32:10**
Generated On: 09 Jun 2021 17:42:27

AEID	USA-US122-2020-MRNA-1273-P30 1000004
Adverse event	PROVISIONAL DIAGNOSIS ONLY - SUDDEN FATAL EVENT, LIKELY MYOCARDIAL INFARCTION
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)*	27 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)*	27 NOV 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	True
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	

US3472001
Folder: Adverse Events
Form: Adverse Events (2)
Data signed: (b) (4) **29 Mar 2021 15:32:10**
Generated On: 09 Jun 2021 17:42:27

	PARTICIPANT FOUND DEAD ON BATHROOM FLOOR ON 11/27/20. TIME OF DEATH NOT YET DETERMINED. CAUSE OF DEATH NOT DETERMINED. REQUESTING FAMILY PERMISSION TO CONDUCT LIMITED POST MORTEM EXAM. 12/3 UPDATE: FAMILY REFUSED POST MORTEM EXAM.
Serious Adverse Event Derived (CSA Programming Field Ony)	1
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

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US3472001
Folder: Adverse Events
Form: Adverse Events (3)
Data signed: (b) (4) **29 Mar 2021 15:32:10**
Generated On: 09 Jun 2021 17:42:27

AEID	
Adverse event	
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)*	
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☐
If not Ongoing, end date *(dd MMM yyyy)*	
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	
Life threatening	
Requires inpatient or prolongation of existing Hospitalization	
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	
Congenital anomaly or birth defect	
Other medically important event	
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	
Concomitant Medication	
Concomitant Procedure	
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)	
Medically Attended AE Derived (CSA Programming Field Only)	
Admitted to ICU Derived (CSA Programming Field Only)	

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination Summary
Data signed: (b) (4) **29 Mar 2021 15:32:10**
Generated On: 09 Jun 2021 17:42:27

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

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

FDA-CBER-2022-1614-1778639

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Data signed: (b) (4) **29 Mar 2021 15:32:10**
Generated On: 09 Jun 2021 17:42:27

Name of Medication	ELIQUIS
Prophylaxis	Yes ■ No ☐
Indication	PROPHYLAXIS FOR VTE
Dose per administration	5
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ■ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 2016
Start date completely unknown	False
Ongoing?	Yes ■ No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐ No ■
Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ■

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Data signed: (b) (4) **29 Mar 2021 15:32:10**
Generated On: 09 Jun 2021 17:42:27

Name of Medication	ATORVASTATIN
Prophylaxis	Yes ○ No ●
Indication	HYPERLIPIDEMIA
Dose per administration	20
Dose unit	mg ● ug ○ mL ○ g ○ IU ○ tablet ○ capsule ○ puff ○ Other ○
If dose unit is Other, specify	
Frequency	once daily ● twice daily ○ three times daily ○ four times daily ○ every other day ○ every week ○ every month ○ as needed ○ once ○ unknown ○ other ○
If frequency is Other, specify	
Route of administration	Oral ● Topical ○ Subcutaneous ○ Transdermal ○ Intraocular ○

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	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 2010
Start date completely unknown	False
Ongoing?	Yes ■ No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐ No ■
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ■

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Data signed: (b) (4) **29 Mar 2021 15:32:10**
Generated On: 09 Jun 2021 17:42:27

Name of Medication	VITAMIN B SUPPLEMENT
Prophylaxis	Yes ■ No ☐
Indication	HEALTH PROMOTION
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 ☐

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	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN SEP 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 ■

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Data signed: (b) (4) **29 Mar 2021 15:32:10**
Generated On: 09 Jun 2021 17:42:27

Name of Medication	DUCOLAX
Prophylaxis	Yes ○ No ●
Indication	CONSTIPATION
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 ○

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	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 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 ☐

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Data signed: (b) (4) **29 Mar 2021 15:32:10**
Generated On: 09 Jun 2021 17:42:27

Name of Medication	COLACE
Prophylaxis	Yes ☐ No ■
Indication	CONSTIPATION
Dose per administration	100
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ■ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 2010
Start date completely unknown	False
Ongoing?	Yes ■
	No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☐

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Data signed: (b) (4) **29 Mar 2021 15:32:10**
Generated On: 09 Jun 2021 17:42:27

Name of Medication	LOSARTIN-HCTZ
Prophylaxis	Yes ☐ No ■
Indication	HYPERTENSION
Dose per administration	100/25
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ■ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

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	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 2005
Start date completely unknown	False
Ongoing?	Yes ■
	No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Data signed: (b) (4) **29 Mar 2021 15:32:10**
Generated On: 09 Jun 2021 17:42:27

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

FDA-CBER-2022-1614-1778652

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 2005
Start date completely unknown	False
Ongoing?	Yes ■
	No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Data signed: (b) (4) **29 Mar 2021 15:32:10**
Generated On: 09 Jun 2021 17:42:27

Name of Medication	INFLUENZA VACCINE
Prophylaxis	Yes ■ No ☐
Indication	PROPHYLAXIS
Dose per administration	0.7
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)*	15 SEP 2020
Start date completely unknown	False
Ongoing?	Yes ☐ No ■
If not Ongoing, End date *(dd MMM yyyy)*	15 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 ☐

US3472001
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures Summary
Data signed: (b) (4) **29 Mar 2021 15:32:10**
Generated On: 09 Jun 2021 17:42:27

Were any concomitant procedures performed?	Yes ☐ No ■

If yes, please complete Concomitant Procedures form.

FDA-CBER-2022-1614-1778656

US3472001
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Data signed: (b) (4) **29 Mar 2021 15:32:10**
Generated On: 09 Jun 2021 17:42:27

Date of study discontinuation/completion *(dd MMM yyyy)*	27 NOV 2020
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)*	27 NOV 2020
Was autopsy performed?	Yes ☐ No ☐ Unknown ■

FDA-CBER-2022-1614-1778657

US3472001
Folder: SAE USA-US122-2020-MRNA-1273-P301000004
Form: Safety Report Form
Data signed: (b) (4) **29 Mar 2021 15:32:10**
Generated On: 09 Jun 2021 17:42:27

SAEID	USA-US122-2020-MRNA-1273-P301000004
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	IAN
Investigator's Last Name	FRANK
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

FDA-CBER-2022-1614-1778658

US3472001
Folder: SAE USA-US122-2020-MRNA-1273-P301000004
Form: Safety Report Form (1)
Data signed: (b) (4) **29 Mar 2021 15:32:10**
Generated On: 09 Jun 2021 17:42:27

SAEID	USA-US122-2020-MRNA-1273-P301000004
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	IAN
Investigator's Last Name	FRANK
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	30/NOV/2020 16:08
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

FDA-CBER-2022-1614-1778659

US3472001
Folder: SAE USA-US122-2020-MRNA-1273-P301000004
Form: Safety Report Form (2)
Data signed: (b) (4) **29 Mar 2021 15:32:10**
Generated On: 09 Jun 2021 17:42:27

SAEID	USA-US122-2020-MRNA-1273-P301000004
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	IAN
Investigator's Last Name	FRANK
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	08/DEC/2020 10:25
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

FDA-CBER-2022-1614-1778660

US3472001
Folder: SAE USA-US122-2020-MRNA-1273-P301000004
Form: Safety Report Form (3)
Data signed: (b) (4) **29 Mar 2021 15:32:10**
Generated On: 09 Jun 2021 17:42:27

SAEID	USA-US122-2020-MRNA-1273-P301000004
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	IAN
Investigator's Last Name	FRANK
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	04/MAR/2021 09:33
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

US3472001 (Prod: Penn Prevention - (CRS))

US3472001
Form: Participant Creation
Generated On: 09 Jun 2021 17:42:27
Participant ID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
User entered 'US3472001'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	31 Aug 2020 13:04:49

FDA-CBER-2022-1614-1778663

US3472001
Form: Participant Creation
Generated On: 09 Jun 2021 17:42:27

mRNA-1273-P301 Completion Guidelines

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19

FDA-CBER-2022-1614-1778664

US3472001
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 17:42:27
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 15:06:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Aug 2020 13:47:20

FDA-CBER-2022-1614-1778665

US3472001
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 17:42:27
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 15:06:33
User entered '31 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	31 Aug 2020 13:04:50

FDA-CBER-2022-1614-1778666

US3472001
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 17:42:27
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 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 15:06:36
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	31 Aug 2020 13:47:20

FDA-CBER-2022-1614-1778667

US3472001
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 17:42:27
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered 'SCRN'	System	31 Aug 2020 13:47:20

FDA-CBER-2022-1614-1778668

US3472001
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:42:27
Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 15:06:51
User entered (b) (6) 1950'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	31 Aug 2020 13:04:51

FDA-CBER-2022-1614-1778669

US3472001
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:42:27
Age

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 15:06:51
User entered '70'	Jie Ho (b) (4)	31 Aug 2020 15:20:37

FDA-CBER-2022-1614-1778670

US3472001
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:42:27
Age Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered 'YEARS'	System	31 Aug 2020 15:20:37

FDA-CBER-2022-1614-1778671

US3472001
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:42:27
Age (Derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered '70'	System	31 Aug 2020 15:23:47

FDA-CBER-2022-1614-1778672

US3472001
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:42:27
Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 15:06:51
User entered 'Male (M)'	Jie Ho (b) (4)	31 Aug 2020 15:20:37

FDA-CBER-2022-1614-1778673

US3472001
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:42:27
Ethnicity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 15:06:51
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Jie Ho (b) (4)	31 Aug 2020 15:20:37

FDA-CBER-2022-1614-1778674

US3472001
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:42:27
White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 15:06:51
User entered '1'	Jie Ho (b) (4)	31 Aug 2020 15:20:37

FDA-CBER-2022-1614-1778675

US3472001
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:42:27
Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 15:06:51
User entered '0'	Jie Ho (b) (4)	31 Aug 2020 15:20:37

FDA-CBER-2022-1614-1778676

US3472001
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:42:27
Asian

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 15:06:51
User entered '0'	Jie Ho (b) (4)	31 Aug 2020 15:20:37

FDA-CBER-2022-1614-1778677

US3472001
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:42:27
American Indian or Alaska Native

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 15:06:51
User entered '0'	Jie Ho (b) (4)	31 Aug 2020 15:20:37

FDA-CBER-2022-1614-1778678

US3472001
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:42:27
Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 15:06:51
User entered '0'	Jie Ho (b) (4)	31 Aug 2020 15:20:37

FDA-CBER-2022-1614-1778679

US3472001
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:42:27
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 15:06:51
User entered '0'	Jie Ho (b) (4)	31 Aug 2020 15:20:37

FDA-CBER-2022-1614-1778680

US3472001
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:42:27
If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 15:06:51
User entered empty.	Jie Ho (b) (4)	31 Aug 2020 15:20:37

FDA-CBER-2022-1614-1778681

US3472001
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:42:27
Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 15:06:51
User entered '0'	Jie Ho (b) (4)	31 Aug 2020 15:20:37

FDA-CBER-2022-1614-1778682

US3472001
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 17:42:27
Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 15:06:51
User entered '0'	Jie Ho (b) (4)	31 Aug 2020 15:20:37

FDA-CBER-2022-1614-1778683

US3472001
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 17:42:27
Date of Informed Consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 15:07:18
User entered '31 Aug 2020'	Jie Ho (b) (4)	31 Aug 2020 15:23:47

FDA-CBER-2022-1614-1778684

US3472001
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 17:42:27
Month and Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered 'Aug 2020'	System	31 Aug 2020 15:23:47

FDA-CBER-2022-1614-1778685

US3472001
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 17:42:27
Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered '2020'	System	31 Aug 2020 15:23:47

FDA-CBER-2022-1614-1778686

US3472001
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 17:42:27
Protocol Version

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 15:07:18
User entered 'Amendment 3 (3)'	Jie Ho (b) (4)	31 Aug 2020 15:23:47

FDA-CBER-2022-1614-1778687

US3472001
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 17:42:27
Was participant enrolled in the study?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 15:07:18
User entered 'Yes (Y)'	Jie Ho (b) (4)	31 Aug 2020 15:23:47

FDA-CBER-2022-1614-1778688

US3472001
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 17:42:27
If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 15:07:18
User entered empty.	Jie Ho (b) (4)	31 Aug 2020 15:23:47

FDA-CBER-2022-1614-1778689

US3472001
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 17:42:27
If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 15:07:18
User entered empty.	Jie Ho (b) (4)	31 Aug 2020 15:23:47

FDA-CBER-2022-1614-1778690

US3472001
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 17:42:27
Was this participant screened previously?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 15:07:18
User entered 'No (N)'	Jie Ho (b) (4)	31 Aug 2020 15:23:47

FDA-CBER-2022-1614-1778691

US3472001
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 17:42:27
If Yes, previous participant number

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 15:07:18
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	31 Aug 2020 13:04:50

FDA-CBER-2022-1614-1778692

US3472001
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 17:42:27
Enrollment Trigger

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered '1'	System	31 Aug 2020 15:23:47

FDA-CBER-2022-1614-1778693

US3472001
Folder: Screening
Form: Inclusion/Exclusion Criteria Summary
Generated On: 09 Jun 2021 17:42:27
Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
DataPoint Un-verified.	(b) (4), (b) (6)	03 Sep 2020 17:25:53
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 17:25:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Aug 2020 13:47:40

FDA-CBER-2022-1614-1778694

US3472001
Folder: Screening
Form: Medical History Summary
Generated On: 09 Jun 2021 17:42:27
Were any significant conditions reported?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:26:09
User entered 'Yes (Y)'	Jie Ho (b) (4)	31 Aug 2020 15:28:42

FDA-CBER-2022-1614-1778695

US3472001
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 17:42:27
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:28:12
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Essential hypertension, LLT: Essential hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 15:32:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 15:32:30
Data point term sent to Coder	System	31 Aug 2020 15:31:27
User entered 'Essential Hypertension'	Jie Ho (b) (4)	31 Aug 2020 15:31:06

FDA-CBER-2022-1614-1778696

US3472001
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 17:42:27
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:28:12
User entered 'un UNK 2005'	Jie Ho (b) (4)	31 Aug 2020 15:31:06

FDA-CBER-2022-1614-1778697

US3472001
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 17:42:27
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:28:12
User entered '0'	Jie Ho (b) (4)	31 Aug 2020 15:31:06

FDA-CBER-2022-1614-1778698

US3472001
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 17:42:27
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:28:12
User entered 'Yes (Y)'	Jie Ho (b) (4)	31 Aug 2020 15:31:06

FDA-CBER-2022-1614-1778699

US3472001
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 17:42:27
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:28:12
User entered empty.	Jie Ho (b) (4)	31 Aug 2020 15:31:06

FDA-CBER-2022-1614-1778700

US3472001
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 17:42:27
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:28:12
User entered '0'	Jie Ho (b) (4)	31 Aug 2020 15:31:06

FDA-CBER-2022-1614-1778701

US3472001
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 17:42:27
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered 'Jan 2005'	System	31 Aug 2020 15:31:06

FDA-CBER-2022-1614-1778702

US3472001
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 17:42:27
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered '2005'	System	31 Aug 2020 15:31:06

FDA-CBER-2022-1614-1778703

US3472001
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 17:42:27
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered empty.	System	31 Aug 2020 15:31:06

FDA-CBER-2022-1614-1778704

US3472001
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 17:42:27
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered empty.	System	31 Aug 2020 15:31:06

FDA-CBER-2022-1614-1778705

US3472001
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 17:42:27
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 17:28:12
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Morbid obesity - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 17:55:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 17:55:38
Data point term sent to Coder	System	31 Aug 2020 17:54:55
User entered 'Morbid Obesity'	Jie Ho (b) (4)	31 Aug 2020 17:54:43

FDA-CBER-2022-1614-1778706

US3472001
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 17:42:27
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:28:12
User entered 'un UNK 2005'	Jie Ho (b) (4)	31 Aug 2020 17:54:43

FDA-CBER-2022-1614-1778707

US3472001
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 17:42:27
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:28:12
User entered '0'	Jie Ho (b) (4)	31 Aug 2020 17:54:43

FDA-CBER-2022-1614-1778708

US3472001
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 17:42:27
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:28:12
User entered 'Yes (Y)'	Jie Ho (b) (4)	31 Aug 2020 17:54:43

FDA-CBER-2022-1614-1778709

US3472001
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 17:42:27
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:28:12
User entered empty.	Jie Ho (b) (4)	31 Aug 2020 17:54:43

FDA-CBER-2022-1614-1778710

US3472001
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 17:42:27
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:28:12
User entered '0'	Jie Ho (b) (4)	31 Aug 2020 17:54:43

FDA-CBER-2022-1614-1778711

US3472001
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 17:42:27
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered 'Jan 2005'	System	31 Aug 2020 17:54:43

FDA-CBER-2022-1614-1778712

US3472001
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 17:42:27
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered '2005'	System	31 Aug 2020 17:54:43

FDA-CBER-2022-1614-1778713

US3472001
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 17:42:27
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered empty.	System	31 Aug 2020 17:54:43

FDA-CBER-2022-1614-1778714

US3472001
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 17:42:27
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered empty.	System	31 Aug 2020 17:54:43

FDA-CBER-2022-1614-1778715

US3472001
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 17:42:27
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 15:56:14
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 15:56:14
User closed query 'CDM requery: Thank you for updating the location, however please also confirm if any Conmeds are ongoing for Osteoarthritis and update the CONEMD form or confirm in the response if no Conmed taken. ' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 06:46:33
Query 'CDM requery: Thank you for updating the location, however please also confirm if any Conmeds are ongoing for Osteoarthritis and update the CONEMD form or confirm in the response if no Conmed taken. ' answered with 'No problem, confirming none taken.' (Site from DM).	Jie Ho (b) (4)	25 Sep 2020 19:04:13
User opened query 'CDM requery: Thank you for updating the location, however please also confirm if any Conmeds are ongoing for Osteoarthritis and update the CONEMD form or confirm in the response if no Conmed taken. ' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 09:09:27
User closed query 'Per DM CLR: Please specify the location of OSTEOARTHRITIS. Review and update medical history diagnosis as appropriate and ensure update to MH is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 09:09:27
Query 'Per DM CLR: Please specify the location of OSTEOARTHRITIS. Review and update medical history diagnosis as appropriate and ensure update to MH is reconciled with any corresponding AE or ConMed entries, if applicable.' answered with 'Updated, thank you.' (Site from DM).	Jie Ho (b) (4)	24 Sep 2020 15:53:44
Data point term sent to Coder	System	24 Sep 2020 15:53:41
DataPoint Un-verified.	Jie Ho (b) (4)	24 Sep 2020 15:53:37
Coding entries removed.	Jie Ho (b) (4)	24 Sep 2020 15:53:37

FDA-CBER-2022-1614-1778716

US3472001
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 17:42:27
Condition

Audit	User	Time (GMT)
User entered 'OSTEOARTHRITIS in both lower extremities' reason for change: Per Query Resolution	Jie Ho (b) (4)	24 Sep 2020 15:53:37
User opened query 'Per DM CLR: Please specify the location of OSTEOARTHRITIS. Review and update medical history diagnosis as appropriate and ensure update to MH is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 20:10:35
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 17:28:12
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 17:56:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 17:56:39
Data point term sent to Coder	System	31 Aug 2020 17:55:55
User entered 'Osteoarthritis'	Jie Ho (b) (4)	31 Aug 2020 17:55:04

FDA-CBER-2022-1614-1778717

US3472001
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 17:42:27
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:28:12
User entered 'un UNK 2005'	Jie Ho (b) (4)	31 Aug 2020 17:55:04

FDA-CBER-2022-1614-1778718

US3472001
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 17:42:27
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:28:12
User entered '0'	Jie Ho (b) (4)	31 Aug 2020 17:55:04

FDA-CBER-2022-1614-1778719

US3472001
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 17:42:27
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:28:12
User entered 'Yes (Y)'	Jie Ho (b) (4)	31 Aug 2020 17:55:04

FDA-CBER-2022-1614-1778720

US3472001
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 17:42:27
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:28:12
User entered empty.	Jie Ho (b) (4)	31 Aug 2020 17:55:04

FDA-CBER-2022-1614-1778721

US3472001
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 17:42:27
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:28:12
User entered '0'	Jie Ho (b) (4)	31 Aug 2020 17:55:04

FDA-CBER-2022-1614-1778722

US3472001
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 17:42:27
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered 'Jan 2005'	System	31 Aug 2020 17:55:04

FDA-CBER-2022-1614-1778723

US3472001
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 17:42:27
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered '2005'	System	31 Aug 2020 17:55:04

FDA-CBER-2022-1614-1778724

US3472001
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 17:42:27
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered empty.	System	31 Aug 2020 17:55:04

FDA-CBER-2022-1614-1778725

US3472001
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 17:42:27
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered empty.	System	31 Aug 2020 17:55:04

FDA-CBER-2022-1614-1778726

US3472001
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 17:42:27
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:28:12
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Cardiac conduction disorders, PT: Wolff-Parkinson-White syndrome, LLT: Wolff-Parkinson-White syndrome - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 09:03:51
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 09:03:51
Data point term sent to Coder	System	31 Aug 2020 17:55:57
User entered 'Wolf Parkinson White Syndrome'	Jie Ho (b) (4)	31 Aug 2020 17:55:28

FDA-CBER-2022-1614-1778727

US3472001
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 17:42:27
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:28:12
User entered 'un UNK 2005'	Jie Ho (b) (4)	31 Aug 2020 17:55:28

FDA-CBER-2022-1614-1778728

US3472001
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 17:42:27
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:28:12
User entered '0'	Jie Ho (b) (4)	31 Aug 2020 17:55:28

FDA-CBER-2022-1614-1778729

US3472001
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 17:42:27
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:28:12
User entered 'Yes (Y)'	Jie Ho (b) (4)	31 Aug 2020 17:55:28

FDA-CBER-2022-1614-1778730

US3472001
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 17:42:27
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:28:12
User entered empty.	Jie Ho (b) (4)	31 Aug 2020 17:55:28

FDA-CBER-2022-1614-1778731

US3472001
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 17:42:27
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:28:12
User entered '0'	Jie Ho (b) (4)	31 Aug 2020 17:55:28

FDA-CBER-2022-1614-1778732

US3472001
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 17:42:27
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered 'Jan 2005'	System	31 Aug 2020 17:55:28

FDA-CBER-2022-1614-1778733

US3472001
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 17:42:27
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered '2005'	System	31 Aug 2020 17:55:28

FDA-CBER-2022-1614-1778734

US3472001
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 17:42:27
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered empty.	System	31 Aug 2020 17:55:28

FDA-CBER-2022-1614-1778735

US3472001
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 17:42:27
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered empty.	System	31 Aug 2020 17:55:28

FDA-CBER-2022-1614-1778736

US3472001
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 17:42:27
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
User closed query 'CDM requery: Thank you for updating the location, however Since this MH event is ongoing please also confirm if any Medications are taken for this event and update the CONMED form or confirm in the response if no Conmed taken.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 06:46:49
Query 'CDM requery: Thank you for updating the location, however Since this MH event is ongoing please also confirm if any Medications are taken for this event and update the CONMED form or confirm in the response if no Conmed taken.' answered with 'No problem, confirming none taken.' (Site from DM).	Jie Ho (b) (4)	25 Sep 2020 19:04:50
User opened query 'CDM requery: Thank you for updating the location, however Since this MH event is ongoing please also confirm if any Medications are taken for this event and update the CONMED form or confirm in the response if no Conmed taken.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 10:03:42
User closed query 'Per DM CLR: Please update the condition to confirm if the RENAL CYST was benign or malignant. Review and update medical history diagnosis as appropriate and ensure update to MH is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 10:03:42
User coded data point as SOC: Renal and urinary disorders, HLGT: Renal disorders (excl nephropathies), HLT: Renal neoplasms, PT: Renal cyst, LLT: Renal cyst - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Sep 2020 15:55:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Sep 2020 15:55:47
Data point term sent to Coder	System	24 Sep 2020 15:54:41

FDA-CBER-2022-1614-1778737

US3472001
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 17:42:27
Condition

Audit	User	Time (GMT)
Query 'Per DM CLR: Please update the condition to confirm if the RENAL CYST was benign or malignant. Review and update medical history diagnosis as appropriate and ensure update to MH is reconciled with any corresponding AE or ConMed entries, if applicable.' answered with 'Updated, thank you.' (Site from DM).	Jie Ho (b) (4)	24 Sep 2020 15:54:17
DataPoint Un-verified.	Jie Ho (b) (4)	24 Sep 2020 15:54:09
Coding entries removed.	Jie Ho (b) (4)	24 Sep 2020 15:54:09
User entered 'Benign RENAL CYST' reason for change: Per Query Resolution	Jie Ho (b) (4)	24 Sep 2020 15:54:09
User opened query 'Per DM CLR: Please update the condition to confirm if the RENAL CYST was benign or malignant. Review and update medical history diagnosis as appropriate and ensure update to MH is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 20:11:00
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 17:28:12
User coded data point as SOC: Renal and urinary disorders, HLGT: Renal disorders (excl nephropathies), HLT: Renal neoplasms, PT: Renal cyst, LLT: Renal cyst - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 17:56:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 17:56:39
Data point term sent to Coder	System	31 Aug 2020 17:55:57
User entered 'Renal Cyst'	Jie Ho (b) (4)	31 Aug 2020 17:55:44

FDA-CBER-2022-1614-1778738

US3472001
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 17:42:27
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:28:12
User entered 'un Aug 2012'	Jie Ho (b) (4)	31 Aug 2020 17:55:44

FDA-CBER-2022-1614-1778739

US3472001
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 17:42:27
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:28:12
User entered '0'	Jie Ho (b) (4)	31 Aug 2020 17:55:44

FDA-CBER-2022-1614-1778740

US3472001
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 17:42:27
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:28:12
User entered 'Yes (Y)'	Jie Ho (b) (4)	31 Aug 2020 17:55:44

FDA-CBER-2022-1614-1778741

US3472001
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 17:42:27
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:28:12
User entered empty.	Jie Ho (b) (4)	31 Aug 2020 17:55:44

FDA-CBER-2022-1614-1778742

US3472001
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 17:42:27
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:28:12
User entered '0'	Jie Ho (b) (4)	31 Aug 2020 17:55:44

FDA-CBER-2022-1614-1778743

US3472001
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 17:42:27
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered 'Aug 2012'	System	31 Aug 2020 17:55:44

FDA-CBER-2022-1614-1778744

US3472001
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 17:42:27
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered '2012'	System	31 Aug 2020 17:55:44

FDA-CBER-2022-1614-1778745

US3472001
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 17:42:27
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered empty.	System	31 Aug 2020 17:55:44

FDA-CBER-2022-1614-1778746

US3472001
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 17:42:27
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered empty.	System	31 Aug 2020 17:55:44

FDA-CBER-2022-1614-1778747

US3472001
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 17:42:27
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 17:28:12
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Sleep apnoea syndrome, LLT: Obstructive sleep apnea syndrome - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 17:57:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 17:57:35
Data point term sent to Coder	System	31 Aug 2020 17:57:01
User entered 'Obstructive Sleep Apnea'	Jie Ho (b) (4)	31 Aug 2020 17:56:03

FDA-CBER-2022-1614-1778748

US3472001
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 17:42:27
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:28:12
User entered 'un UNK 2012'	Jie Ho (b) (4)	31 Aug 2020 17:56:03

FDA-CBER-2022-1614-1778749

US3472001
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 17:42:27
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:28:12
User entered '0'	Jie Ho (b) (4)	31 Aug 2020 17:56:03

FDA-CBER-2022-1614-1778750

US3472001
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 17:42:27
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:28:12
User entered 'Yes (Y)'	Jie Ho (b) (4)	31 Aug 2020 17:56:03

FDA-CBER-2022-1614-1778751

US3472001
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 17:42:27
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:28:12
User entered empty.	Jie Ho (b) (4)	31 Aug 2020 17:56:03

FDA-CBER-2022-1614-1778752

US3472001
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 17:42:27
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:28:12
User entered '0'	Jie Ho (b) (4)	31 Aug 2020 17:56:03

FDA-CBER-2022-1614-1778753

US3472001
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 17:42:27
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered 'Jan 2012'	System	31 Aug 2020 17:56:03

FDA-CBER-2022-1614-1778754

US3472001
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 17:42:27
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered '2012'	System	31 Aug 2020 17:56:03

FDA-CBER-2022-1614-1778755

US3472001
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 17:42:27
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered empty.	System	31 Aug 2020 17:56:03

FDA-CBER-2022-1614-1778756

US3472001
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 17:42:27
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered empty.	System	31 Aug 2020 17:56:03

FDA-CBER-2022-1614-1778757

US3472001
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 17:42:27
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 17:28:12
User coded data point as SOC: Vascular disorders, HLGT: Arteriosclerosis, stenosis, vascular insufficiency and necrosis, HLT: Aortic necrosis and vascular insufficiency, PT: Aortic stenosis, LLT: Aortic stenosis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 17:57:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 17:57:36
Data point term sent to Coder	System	31 Aug 2020 17:57:01
User entered 'Mild Aortic Stenosis'	Jie Ho (b) (4)	31 Aug 2020 17:56:26

FDA-CBER-2022-1614-1778758

US3472001
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 17:42:27
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:28:12
User entered 'un UNK 2016'	Jie Ho (b) (4)	31 Aug 2020 17:56:26

FDA-CBER-2022-1614-1778759

US3472001
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 17:42:27
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:28:12
User entered '0'	Jie Ho (b) (4)	31 Aug 2020 17:56:26

FDA-CBER-2022-1614-1778760

US3472001
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 17:42:27
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:28:12
User entered 'Yes (Y)'	Jie Ho (b) (4)	31 Aug 2020 17:56:26

FDA-CBER-2022-1614-1778761

US3472001
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 17:42:27
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:28:12
User entered empty.	Jie Ho (b) (4)	31 Aug 2020 17:56:26

FDA-CBER-2022-1614-1778762

US3472001
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 17:42:27
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:28:12
User entered '0'	Jie Ho (b) (4)	31 Aug 2020 17:56:26

FDA-CBER-2022-1614-1778763

US3472001
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 17:42:27
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered 'Jan 2016'	System	31 Aug 2020 17:56:26

FDA-CBER-2022-1614-1778764

US3472001
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 17:42:27
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered '2016'	System	31 Aug 2020 17:56:26

FDA-CBER-2022-1614-1778765

US3472001
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 17:42:27
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered empty.	System	31 Aug 2020 17:56:26

FDA-CBER-2022-1614-1778766

US3472001
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 17:42:27
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered empty.	System	31 Aug 2020 17:56:26

FDA-CBER-2022-1614-1778767

US3472001
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 17:42:27
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 17:28:12
User coded data point as SOC: Cardiac disorders, HLGT: Myocardial disorders, HLT: Myocardial disorders NEC, PT: Left ventricular hypertrophy, LLT: Left ventricular hypertrophy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 17:57:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 17:57:36
Data point term sent to Coder	System	31 Aug 2020 17:57:04
User entered 'Left Ventricular Hypertrophy'	Jie Ho (b) (4)	31 Aug 2020 17:56:48

FDA-CBER-2022-1614-1778768

US3472001
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 17:42:27
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:28:12
User entered 'un UNK 2016'	Jie Ho (b) (4)	31 Aug 2020 17:56:48

FDA-CBER-2022-1614-1778769

US3472001
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 17:42:27
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:28:12
User entered '0'	Jie Ho (b) (4)	31 Aug 2020 17:56:48

FDA-CBER-2022-1614-1778770

US3472001
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 17:42:27
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:28:12
User entered 'Yes (Y)'	Jie Ho (b) (4)	31 Aug 2020 17:56:48

FDA-CBER-2022-1614-1778771

US3472001
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 17:42:27
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:28:12
User entered empty.	Jie Ho (b) (4)	31 Aug 2020 17:56:48

FDA-CBER-2022-1614-1778772

US3472001
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 17:42:27
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:28:12
User entered '0'	Jie Ho (b) (4)	31 Aug 2020 17:56:48

FDA-CBER-2022-1614-1778773

US3472001
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 17:42:27
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered 'Jan 2016'	System	31 Aug 2020 17:56:48

FDA-CBER-2022-1614-1778774

US3472001
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 17:42:27
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered '2016'	System	31 Aug 2020 17:56:48

FDA-CBER-2022-1614-1778775

US3472001
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 17:42:27
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered empty.	System	31 Aug 2020 17:56:48

FDA-CBER-2022-1614-1778776

US3472001
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 17:42:27
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered empty.	System	31 Aug 2020 17:56:48

FDA-CBER-2022-1614-1778777

US3472001
Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 17:42:27
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 08:58:25
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' answered with 'Per correspondence with NP this condition is treated by PCP, including anticoagulation with apixaban.' (Site from DM).	Jie Ho (b) (4)	24 Sep 2020 15:57:34
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 20:11:57
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 17:28:12
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: Atrial fibrillation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 17:59:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 17:59:37
Data point term sent to Coder	System	31 Aug 2020 17:58:05
User entered 'Atrial Fibrillation'	Jie Ho (b) (4)	31 Aug 2020 17:57:06

FDA-CBER-2022-1614-1778778

US3472001
Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 17:42:27
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:28:12
User entered 'un UNK 2016'	Jie Ho (b) (4)	31 Aug 2020 17:57:06

FDA-CBER-2022-1614-1778779

US3472001
Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 17:42:27
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:28:12
User entered '0'	Jie Ho (b) (4)	31 Aug 2020 17:57:06

FDA-CBER-2022-1614-1778780

US3472001
Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 17:42:27
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:28:12
User entered 'Yes (Y)'	Jie Ho (b) (4)	31 Aug 2020 17:57:06

FDA-CBER-2022-1614-1778781

US3472001
Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 17:42:27
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:28:12
User entered empty.	Jie Ho (b) (4)	31 Aug 2020 17:57:06

FDA-CBER-2022-1614-1778782

US3472001
Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 17:42:27
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:28:12
User entered '0'	Jie Ho (b) (4)	31 Aug 2020 17:57:06

FDA-CBER-2022-1614-1778783

US3472001
Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 17:42:27
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered 'Jan 2016'	System	31 Aug 2020 17:57:06

FDA-CBER-2022-1614-1778784

US3472001
Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 17:42:27
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered '2016'	System	31 Aug 2020 17:57:06

FDA-CBER-2022-1614-1778785

US3472001
Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 17:42:27
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered empty.	System	31 Aug 2020 17:57:06

FDA-CBER-2022-1614-1778786

US3472001
Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 17:42:27
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered empty.	System	31 Aug 2020 17:57:06

FDA-CBER-2022-1614-1778787

US3472001
Folder: Screening
Form: Medical History (10)
Generated On: 09 Jun 2021 17:42:27
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 17:28:12
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 17:59:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 17:59:36
Data point term sent to Coder	System	31 Aug 2020 17:58:07
User entered 'Hyperlipidemia'	Jie Ho (b) (4)	31 Aug 2020 17:57:33

FDA-CBER-2022-1614-1778788

US3472001
Folder: Screening
Form: Medical History (10)
Generated On: 09 Jun 2021 17:42:27
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:28:12
User entered empty.	Jie Ho (b) (4)	31 Aug 2020 17:57:33

FDA-CBER-2022-1614-1778789

US3472001
Folder: Screening
Form: Medical History (10)
Generated On: 09 Jun 2021 17:42:27
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:28:12
User entered '1'	Jie Ho (b) (4)	31 Aug 2020 17:57:33

FDA-CBER-2022-1614-1778790

US3472001
Folder: Screening
Form: Medical History (10)
Generated On: 09 Jun 2021 17:42:27
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:28:12
User entered 'Yes (Y)'	Jie Ho (b) (4)	31 Aug 2020 17:57:33

FDA-CBER-2022-1614-1778791

US3472001
Folder: Screening
Form: Medical History (10)
Generated On: 09 Jun 2021 17:42:27
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:28:12
User entered empty.	Jie Ho (b) (4)	31 Aug 2020 17:57:33

FDA-CBER-2022-1614-1778792

US3472001
Folder: Screening
Form: Medical History (10)
Generated On: 09 Jun 2021 17:42:27
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:28:12
User entered '0'	Jie Ho (b) (4)	31 Aug 2020 17:57:33

FDA-CBER-2022-1614-1778793

US3472001
Folder: Screening
Form: Medical History (10)
Generated On: 09 Jun 2021 17:42:27
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered empty.	System	31 Aug 2020 17:57:33

FDA-CBER-2022-1614-1778794

US3472001
Folder: Screening
Form: Medical History (10)
Generated On: 09 Jun 2021 17:42:27
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered empty.	System	31 Aug 2020 17:57:33

FDA-CBER-2022-1614-1778795

US3472001
Folder: Screening
Form: Medical History (10)
Generated On: 09 Jun 2021 17:42:27
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered empty.	System	31 Aug 2020 17:57:33

FDA-CBER-2022-1614-1778796

US3472001
Folder: Screening
Form: Medical History (10)
Generated On: 09 Jun 2021 17:42:27
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered empty.	System	31 Aug 2020 17:57:33

FDA-CBER-2022-1614-1778797

US3472001
Folder: Screening
Form: Medical History (11)
Generated On: 09 Jun 2021 17:42:27
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Constipation, LLT: Constipation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Oct 2020 20:55:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Oct 2020 20:55:22
Data point term sent to Coder	System	12 Oct 2020 20:54:20
User entered 'constipation'	Jie Ho (b) (4)	12 Oct 2020 20:54:08

FDA-CBER-2022-1614-1778798

US3472001
Folder: Screening
Form: Medical History (11)
Generated On: 09 Jun 2021 17:42:27
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
User entered 'un UNK 2010'	Jie Ho (b) (4)	12 Oct 2020 20:54:08

FDA-CBER-2022-1614-1778799

US3472001
Folder: Screening
Form: Medical History (11)
Generated On: 09 Jun 2021 17:42:27
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
User entered '0'	Jie Ho (b) (4)	12 Oct 2020 20:54:08

FDA-CBER-2022-1614-1778800

US3472001
Folder: Screening
Form: Medical History (11)
Generated On: 09 Jun 2021 17:42:27
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
User entered 'Yes (Y)'	Jie Ho (b) (4)	12 Oct 2020 20:54:08

FDA-CBER-2022-1614-1778801

US3472001
Folder: Screening
Form: Medical History (11)
Generated On: 09 Jun 2021 17:42:27
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
User entered empty.	Jie Ho (b) (4)	12 Oct 2020 20:54:08

FDA-CBER-2022-1614-1778802

US3472001
Folder: Screening
Form: Medical History (11)
Generated On: 09 Jun 2021 17:42:27
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
User entered '0'	Jie Ho (b) (4)	12 Oct 2020 20:54:08

FDA-CBER-2022-1614-1778803

US3472001
Folder: Screening
Form: Medical History (11)
Generated On: 09 Jun 2021 17:42:27
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered 'Jan 2010'	System	12 Oct 2020 20:54:08

FDA-CBER-2022-1614-1778804

US3472001
Folder: Screening
Form: Medical History (11)
Generated On: 09 Jun 2021 17:42:27
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered '2010'	System	12 Oct 2020 20:54:08

FDA-CBER-2022-1614-1778805

US3472001
Folder: Screening
Form: Medical History (11)
Generated On: 09 Jun 2021 17:42:27
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered empty.	System	12 Oct 2020 20:54:08

FDA-CBER-2022-1614-1778806

US3472001
Folder: Screening
Form: Medical History (11)
Generated On: 09 Jun 2021 17:42:27
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered empty.	System	12 Oct 2020 20:54:08

FDA-CBER-2022-1614-1778807

US3472001
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:42:27
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
User entered 'Yes (Y)'	Jie Ho (b) (4)	31 Aug 2020 16:31:10

FDA-CBER-2022-1614-1778808

US3472001
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:42:27
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 15:36:36
User entered '31 Aug 2020'	Jie Ho (b) (4)	31 Aug 2020 16:31:10

FDA-CBER-2022-1614-1778809

US3472001
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:42:27
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
User entered '8:18'	Jie Ho (b) (4)	31 Aug 2020 16:31:10

FDA-CBER-2022-1614-1778810

US3472001
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:42:27
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered '31 Aug 2020 8:18'	System	31 Aug 2020 16:31:10

FDA-CBER-2022-1614-1778811

US3472001
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:42:27
Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
User entered '63' in reason for change: Data Entry Error	Jie Ho (b) (4)	31 Aug 2020 18:39:04
User entered '63.6' in	Jie Ho (b) (4)	31 Aug 2020 16:31:10
DataPoint set to visible.	System	31 Aug 2020 15:23:47

FDA-CBER-2022-1614-1778812

US3472001
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:42:27
Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 15:36:50
User entered '120.7' kg	Jie Ho (b) (4)	31 Aug 2020 16:31:10
DataPoint set to visible.	System	31 Aug 2020 15:23:47

FDA-CBER-2022-1614-1778813

US3472001
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:42:27
BMI *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered '47.13665'	System	31 Aug 2020 18:39:04
User entered '46.25148'	System	31 Aug 2020 16:31:10
DataPoint set to visible.	System	31 Aug 2020 15:23:47

FDA-CBER-2022-1614-1778814

US3472001
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:42:27
BMI units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered 'kg/m2'	System	31 Aug 2020 16:31:10
DataPoint set to visible.	System	31 Aug 2020 15:23:47

FDA-CBER-2022-1614-1778815

US3472001
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:42:27
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
User entered missing code ND - Not Done.	Jie Ho (b) (4)	31 Aug 2020 16:31:10

FDA-CBER-2022-1614-1778816

US3472001
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:42:27
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
User entered empty.	Jie Ho (b) (4)	31 Aug 2020 16:31:10

FDA-CBER-2022-1614-1778817

US3472001
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:42:27
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
User entered empty.	Jie Ho (b) (4)	31 Aug 2020 16:31:10

FDA-CBER-2022-1614-1778818

US3472001
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:42:27
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
User closed query 'Data is required. Please provide.' (Site from System).	System	31 Aug 2020 16:31:20
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	31 Aug 2020 16:31:20
User entered missing code ND - Not Done; reason for change Data Entry Error	Jie Ho (b) (4)	31 Aug 2020 16:31:20
User opened query 'Data is required. Please provide.' (Site from System).	System	31 Aug 2020 16:31:10
User entered empty.	Jie Ho (b) (4)	31 Aug 2020 16:31:10

FDA-CBER-2022-1614-1778819

US3472001
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:42:27
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered 'bpm'	System	31 Aug 2020 16:31:20
User entered empty.	System	31 Aug 2020 16:31:10

FDA-CBER-2022-1614-1778820

US3472001
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:42:27
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
User closed query 'Data is required. Please provide.' (Site from System).	System	31 Aug 2020 16:31:20
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	31 Aug 2020 16:31:20
User entered missing code ND - Not Done; reason for change Data Entry Error	Jie Ho (b) (4)	31 Aug 2020 16:31:20
User opened query 'Data is required. Please provide.' (Site from System).	System	31 Aug 2020 16:31:10
User entered empty.	Jie Ho (b) (4)	31 Aug 2020 16:31:10

FDA-CBER-2022-1614-1778821

US3472001
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:42:27
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered 'breaths/min'	System	31 Aug 2020 16:31:20
User entered empty.	System	31 Aug 2020 16:31:10

FDA-CBER-2022-1614-1778822

US3472001
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:42:27
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
User closed query 'Data is required. Please provide.' (Site from System).	System	31 Aug 2020 16:31:20
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	31 Aug 2020 16:31:20
User entered missing code ND - Not Done; reason for change Data Entry Error	Jie Ho (b) (4)	31 Aug 2020 16:31:20
User opened query 'Data is required. Please provide.' (Site from System).	System	31 Aug 2020 16:31:10
User entered empty.	Jie Ho (b) (4)	31 Aug 2020 16:31:10

FDA-CBER-2022-1614-1778823

US3472001
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:42:27
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered 'mmHg'	System	31 Aug 2020 16:31:20
User entered empty.	System	31 Aug 2020 16:31:10

FDA-CBER-2022-1614-1778824

US3472001
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:42:27
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
User closed query 'Data is required. Please provide.' (Site from System).	System	31 Aug 2020 16:31:20
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	31 Aug 2020 16:31:20
User entered missing code ND - Not Done; reason for change Data Entry Error	Jie Ho (b) (4)	31 Aug 2020 16:31:20
User opened query 'Data is required. Please provide.' (Site from System).	System	31 Aug 2020 16:31:10
User entered empty.	Jie Ho (b) (4)	31 Aug 2020 16:31:10

FDA-CBER-2022-1614-1778825

US3472001
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:42:27
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered 'mmHg'	System	31 Aug 2020 16:31:20
User entered empty.	System	31 Aug 2020 16:31:10

FDA-CBER-2022-1614-1778826

US3472001
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:42:27
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19

FDA-CBER-2022-1614-1778827

US3472001
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 17:42:27
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19

FDA-CBER-2022-1614-1778828

US3472001
Folder: Screening
Form: Physical Examination
Generated On: 09 Jun 2021 17:42:27
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:28:28
User entered 'Yes (Y)'	Jie Ho (b) (4)	31 Aug 2020 15:40:30

FDA-CBER-2022-1614-1778829

US3472001
Folder: Screening
Form: Physical Examination
Generated On: 09 Jun 2021 17:42:27
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:28:28
User entered '31 Aug 2020'	Jie Ho (b) (4)	31 Aug 2020 15:40:30

FDA-CBER-2022-1614-1778830

US3472001
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:42:27
Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:33:00
User entered 'No (N)'	Jie Ho (b) (4)	31 Aug 2020 15:41:52

FDA-CBER-2022-1614-1778831

US3472001
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:42:27
Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:33:00
User entered 'No (N)'	Jie Ho (b) (4)	31 Aug 2020 15:41:52

FDA-CBER-2022-1614-1778832

US3472001
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:42:27

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:33:00
User entered 'No (N)'	Jie Ho (b) (4)	31 Aug 2020 15:41:52

FDA-CBER-2022-1614-1778833

US3472001
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:42:27
Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:33:00
User entered 'No (N)'	Jie Ho (b) (4)	31 Aug 2020 15:41:52

FDA-CBER-2022-1614-1778834

US3472001
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:42:27
Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:33:00
User entered 'No (N)'	Jie Ho (b) (4)	31 Aug 2020 15:41:52

FDA-CBER-2022-1614-1778835

US3472001
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:42:27
Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:33:00
User entered 'No (N)'	Jie Ho (b) (4)	31 Aug 2020 15:41:52

FDA-CBER-2022-1614-1778836

US3472001
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:42:27
Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:33:00
User entered 'No (N)'	Jie Ho (b) (4)	31 Aug 2020 15:41:52

US3472001
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:42:27
Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 17:33:00
User entered 'No (N)'	Jie Ho (b) (4)	31 Aug 2020 15:41:52

FDA-CBER-2022-1614-1778838

US3472001
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:42:27
Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:33:00
User entered 'No (N)'	Jie Ho (b) (4)	31 Aug 2020 15:41:52

FDA-CBER-2022-1614-1778839

US3472001
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:42:27
Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:33:00
User entered 'Yes (Y)'	Jie Ho (b) (4)	31 Aug 2020 15:41:52

FDA-CBER-2022-1614-1778840

US3472001
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:42:27
Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:33:00
User entered 'No (N)'	Jie Ho (b) (4)	31 Aug 2020 15:41:52

US3472001
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:42:27
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:33:00
User entered 'No (N)'	Jie Ho (b) (4)	31 Aug 2020 15:41:52

FDA-CBER-2022-1614-1778842

US3472001
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:42:27
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:33:00
User entered empty.	Jie Ho (b) (4)	31 Aug 2020 15:41:52

FDA-CBER-2022-1614-1778843

US3472001
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:42:27
No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
User entered '0'	Jie Ho (b) (4)	31 Aug 2020 15:41:52

FDA-CBER-2022-1614-1778844

US3472001
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:42:27
Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:33:00
User entered '0'	Jie Ho (b) (4)	31 Aug 2020 15:41:52

FDA-CBER-2022-1614-1778845

US3472001
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:42:27

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:33:00
User entered '0'	Jie Ho (b) (4)	31 Aug 2020 15:41:52

FDA-CBER-2022-1614-1778846

US3472001
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:42:27
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:33:00
User entered '0'	Jie Ho (b) (4)	31 Aug 2020 15:41:52

FDA-CBER-2022-1614-1778847

US3472001
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:42:27
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 17:33:00
User entered '1'	Jie Ho (b) (4)	31 Aug 2020 15:41:52

FDA-CBER-2022-1614-1778848

US3472001
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:42:27
Resides in a single family home (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:33:00
User entered '0'	Jie Ho (b) (4)	31 Aug 2020 15:41:52

FDA-CBER-2022-1614-1778849

US3472001
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:42:27
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
User entered '0'	Jie Ho (b) (4)	31 Aug 2020 15:41:52

FDA-CBER-2022-1614-1778850

US3472001
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 17:42:27
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:33:00
User entered empty.	Jie Ho (b) (4)	31 Aug 2020 15:41:52

FDA-CBER-2022-1614-1778851

US3472001
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 17:42:27
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 17:33:24
User entered 'Yes (Y)'	Debora Dunbar (b) (4) (b) (4)	31 Aug 2020 15:26:46

FDA-CBER-2022-1614-1778852

US3472001
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 17:42:27
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 17:33:24
User entered '31 Aug 2020'	Debora Dunbar (b) (4) (b) (4)	31 Aug 2020 15:26:46

FDA-CBER-2022-1614-1778853

US3472001
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 17:42:27
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 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 17:33:24
User entered 'Clinic (Clinic)'	Debora Dunbar (b) (4) (b) (4)	31 Aug 2020 15:26:46

FDA-CBER-2022-1614-1778854

US3472001
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 17:42:27
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered 'VISIT1'	System	31 Aug 2020 15:26:46

FDA-CBER-2022-1614-1778855

US3472001
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 17:42:27
What was the date of randomization? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 17:34:15
User entered '31 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	31 Aug 2020 13:09:38

FDA-CBER-2022-1614-1778856

US3472001
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 17:42:27
What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 17:34:15
User entered '189047'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	31 Aug 2020 13:09:38

FDA-CBER-2022-1614-1778857

US3472001
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 17:42:27
In what Cohort was the participant enrolled?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 17:34:15
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	31 Aug 2020 13:09:38

FDA-CBER-2022-1614-1778858

US3472001

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:42:27

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)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 17:34:15
User entered 'No (N)'	Jie Ho (b) (4)	31 Aug 2020 17:28:09

US3472001
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 17:42:27

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)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:34:15
User entered 'Yes (Y)'	Jie Ho (b) (4)	31 Aug 2020 17:28:09

FDA-CBER-2022-1614-1778860

US3472001
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 17:42:27
Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:34:15
User entered 'Yes (Y)'	Jie Ho (b) (4)	31 Aug 2020 17:28:09

FDA-CBER-2022-1614-1778861

US3472001
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 17:42:27
Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:34:15
User entered 'No (N)'	Jie Ho (b) (4)	31 Aug 2020 17:28:09

FDA-CBER-2022-1614-1778862

US3472001
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 17:42:27
Liver Disease

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:34:15
User entered 'No (N)'	Jie Ho (b) (4)	31 Aug 2020 17:28:09

FDA-CBER-2022-1614-1778863

US3472001
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 17:42:27
Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
User entered 'No (N)'	Jie Ho (b) (4)	20 Sep 2020 15:50:13
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 08:40:22
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:40:20

FDA-CBER-2022-1614-1778864

US3472001
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 17:42:27
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
User entered missing code ND - Not Done.	Jie Ho (b) (4)	31 Aug 2020 16:46:21

FDA-CBER-2022-1614-1778865

US3472001
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 17:42:27
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
User entered missing code ND - Not Done.	Jie Ho (b) (4)	31 Aug 2020 16:46:21

FDA-CBER-2022-1614-1778866

US3472001
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 17:42:27
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
User entered missing code ND - Not Done.	Jie Ho (b) (4)	31 Aug 2020 16:46:21

FDA-CBER-2022-1614-1778867

US3472001
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 17:42:27
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
User entered missing code ND - Not Done.	Jie Ho (b) (4)	31 Aug 2020 16:46:21

FDA-CBER-2022-1614-1778868

US3472001
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:42:27
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User accepted default value 'Pre-Dose (PREDOSE)'	Jie Ho (b) (4)	31 Aug 2020 16:46:21

FDA-CBER-2022-1614-1778869

US3472001
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:42:27
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
User entered 'Yes (Y)'	Jie Ho (b) (4)	31 Aug 2020 16:46:21

FDA-CBER-2022-1614-1778870

US3472001
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:42:27
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
User entered '31 Aug 2020'	Jie Ho (b) (4)	31 Aug 2020 16:46:21

FDA-CBER-2022-1614-1778871

US3472001
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:42:27
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
User entered '8:18'	Jie Ho (b) (4)	31 Aug 2020 16:46:21

FDA-CBER-2022-1614-1778872

US3472001
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:42:27
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered '31 Aug 2020 8:18'	System	31 Aug 2020 16:46:21

FDA-CBER-2022-1614-1778873

US3472001
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:42:27
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
User entered '37.2' C	Jie Ho (b) (4)	31 Aug 2020 16:46:21

FDA-CBER-2022-1614-1778874

US3472001
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:42:27
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
User entered 'Oral (Oral)'	Jie Ho (b) (4)	31 Aug 2020 16:46:21

FDA-CBER-2022-1614-1778875

US3472001
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:42:27
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
User entered empty.	Jie Ho (b) (4)	31 Aug 2020 16:46:21

FDA-CBER-2022-1614-1778876

US3472001
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:42:27
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
User entered '87'	Jie Ho (b) (4)	31 Aug 2020 16:46:21

FDA-CBER-2022-1614-1778877

US3472001
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:42:27
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered 'bpm'	System	31 Aug 2020 16:46:21

FDA-CBER-2022-1614-1778878

US3472001
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:42:27
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
User entered '16'	Jie Ho (b) (4)	31 Aug 2020 16:46:21

FDA-CBER-2022-1614-1778879

US3472001
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:42:27
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered 'breaths/min'	System	31 Aug 2020 16:46:21

FDA-CBER-2022-1614-1778880

US3472001
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:42:27
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
User entered '126'	Jie Ho (b) (4)	31 Aug 2020 16:46:21

FDA-CBER-2022-1614-1778881

US3472001
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:42:27
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered 'mmHg'	System	31 Aug 2020 16:46:21

FDA-CBER-2022-1614-1778882

US3472001
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:42:27
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
User entered '80'	Jie Ho (b) (4)	31 Aug 2020 16:46:21

FDA-CBER-2022-1614-1778883

US3472001
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:42:27
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered 'mmHg'	System	31 Aug 2020 16:46:21

FDA-CBER-2022-1614-1778884

US3472001
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 17:42:27
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
User entered missing code ND - Not Done.	Jie Ho (b) (4)	31 Aug 2020 16:46:21

FDA-CBER-2022-1614-1778885

US3472001
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 17:42:27
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
User entered missing code ND - Not Done.	Jie Ho (b) (4)	31 Aug 2020 16:46:21

FDA-CBER-2022-1614-1778886

US3472001
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:42:27
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User accepted default value 'Post-Dose (POSTDOSE)'	Jie Ho (b) (4)	31 Aug 2020 16:46:21

FDA-CBER-2022-1614-1778887

US3472001
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:42:27
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
User entered 'Yes (Y)'	Jie Ho (b) (4)	31 Aug 2020 16:46:21

FDA-CBER-2022-1614-1778888

US3472001
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:42:27
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
User entered '31 Aug 2020'	Jie Ho (b) (4)	31 Aug 2020 16:46:21

FDA-CBER-2022-1614-1778889

US3472001
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:42:27
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
User entered '11:50'	Jie Ho (b) (4)	31 Aug 2020 16:46:21

FDA-CBER-2022-1614-1778890

US3472001
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:42:27
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered '31 Aug 2020 11:50'	System	31 Aug 2020 16:46:21

FDA-CBER-2022-1614-1778891

US3472001
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:42:27
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
User entered '36.2' C	Jie Ho (b) (4)	31 Aug 2020 16:46:21

FDA-CBER-2022-1614-1778892

US3472001
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:42:27
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
User entered 'Oral (Oral)'	Jie Ho (b) (4)	31 Aug 2020 16:46:21

FDA-CBER-2022-1614-1778893

US3472001
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:42:27
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
User entered empty.	Jie Ho (b) (4)	31 Aug 2020 16:46:21

FDA-CBER-2022-1614-1778894

US3472001
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:42:27
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
User entered '85'	Jie Ho (b) (4)	31 Aug 2020 16:46:21

FDA-CBER-2022-1614-1778895

US3472001
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:42:27
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered 'bpm'	System	31 Aug 2020 16:46:21

FDA-CBER-2022-1614-1778896

US3472001
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:42:27
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
User entered '18'	Jie Ho (b) (4)	31 Aug 2020 16:46:21

FDA-CBER-2022-1614-1778897

US3472001
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:42:27
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered 'breaths/min'	System	31 Aug 2020 16:46:21

FDA-CBER-2022-1614-1778898

US3472001
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:42:27
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
User entered '106'	Jie Ho (b) (4)	31 Aug 2020 16:46:21

FDA-CBER-2022-1614-1778899

US3472001
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:42:27
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered 'mmHg'	System	31 Aug 2020 16:46:21

FDA-CBER-2022-1614-1778900

US3472001
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:42:27
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
User entered '65'	Jie Ho (b) (4)	31 Aug 2020 16:46:21

FDA-CBER-2022-1614-1778901

US3472001
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:42:27
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered 'mmHg'	System	31 Aug 2020 16:46:21

FDA-CBER-2022-1614-1778902

US3472001
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 09 Jun 2021 17:42:27
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:01:46
Query 'Per source records, physical examination was performed on 8/31/2020. Please confirm.' canceled (Site from CRA).	(b) (4), (b) (6)	03 Sep 2020 19:01:37
User opened query 'Per source records, physical examination was performed on 8/31/2020. Please confirm.' (Site from CRA).	(b) (4), (b) (6)	03 Sep 2020 17:36:28
User entered 'No (N)' reason for change: Data Entry Error	Jie Ho (b) (4)	01 Sep 2020 15:55:51
User entered 'Yes (Y)'	Jie Ho (b) (4)	31 Aug 2020 17:28:28

FDA-CBER-2022-1614-1778903

US3472001
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 09 Jun 2021 17:42:27
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:01:46
User entered empty; reason for change Data Entry Error	Jie Ho (b) (4)	01 Sep 2020 15:55:51
User entered '31 Aug 2020'	Jie Ho (b) (4)	31 Aug 2020 17:28:28

FDA-CBER-2022-1614-1778904

US3472001
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 17:42:27
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 17:37:41
User entered 'Yes (Y)'	Debora Dunbar (b) (4) (b) (4)	31 Aug 2020 15:27:47

FDA-CBER-2022-1614-1778905

US3472001
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 17:42:27
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 17:37:41
User entered empty.	Debora Dunbar (b) (4) (b) (4)	31 Aug 2020 15:27:47

FDA-CBER-2022-1614-1778906

US3472001
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 17:42:27

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)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 17:37:41
User entered empty.	Debora Dunbar (b) (4) (b) (4)	31 Aug 2020 15:27:47

FDA-CBER-2022-1614-1778907

US3472001
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 17:42:27
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered 'MRNA-1273 OR PLACEBO'	System	31 Aug 2020 15:27:47

FDA-CBER-2022-1614-1778908

US3472001
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 17:42:27
What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 17:37:41
User entered '31 Aug 2020'	Debora Dunbar (b) (4) (b) (4)	31 Aug 2020 15:27:47

FDA-CBER-2022-1614-1778909

US3472001
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 17:42:27
What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 17:37:41
User entered '11:21'	Debora Dunbar (b) (4) (b) (4)	31 Aug 2020 15:27:47

FDA-CBER-2022-1614-1778910

US3472001
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 17:42:27
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered '31 Aug 2020 11:21'	System	31 Aug 2020 15:27:47

FDA-CBER-2022-1614-1778911

US3472001
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 17:42:27
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 17:37:41
User entered 'Right Arm (RIGHT ARM)'	Debora Dunbar (b) (4) (b) (4)	31 Aug 2020 15:27:47

FDA-CBER-2022-1614-1778912

US3472001
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 17:42:27
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 17:37:41
User entered 'ONCE'	System	31 Aug 2020 15:27:47

FDA-CBER-2022-1614-1778913

US3472001
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 17:42:27
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered 'INTRAMUSCULAR'	System	31 Aug 2020 15:27:47

FDA-CBER-2022-1614-1778914

US3472001
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 17:42:27
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:39:47
User entered 'Yes (Y)'	Jie Ho (b) (4)	31 Aug 2020 17:29:58

FDA-CBER-2022-1614-1778915

US3472001
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 17:42:27
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:39:47
User entered '31 Aug 2020'	Jie Ho (b) (4)	31 Aug 2020 17:29:58

FDA-CBER-2022-1614-1778916

US3472001
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 17:42:27
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:39:47
User entered '9:55'	Jie Ho (b) (4)	31 Aug 2020 17:29:58

FDA-CBER-2022-1614-1778917

US3472001
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 17:42:27
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered '31 Aug 2020 9:55'	System	31 Aug 2020 17:29:58

FDA-CBER-2022-1614-1778918

US3472001
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab
Generated On: 09 Jun 2021 17:42:27
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:40:02
User entered '31 Aug 2020'	Jie Ho (b) (4)	31 Aug 2020 17:31:23

FDA-CBER-2022-1614-1778919

US3472001
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 17:42:27
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Jie Ho (b) (4)	31 Aug 2020 17:31:23

FDA-CBER-2022-1614-1778920

US3472001
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 17:42:27
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:40:02
User entered 'Yes (Y)'	Jie Ho (b) (4)	31 Aug 2020 17:31:23

FDA-CBER-2022-1614-1778921

US3472001
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 17:42:27
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:40:02
User entered '9:05'	Jie Ho (b) (4)	31 Aug 2020 17:31:23

FDA-CBER-2022-1614-1778922

US3472001
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 17:42:27
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered '31 Aug 2020 9:05'	System	31 Aug 2020 17:31:23

FDA-CBER-2022-1614-1778923

US3472001
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 17:42:27
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Jie Ho (b) (4)	31 Aug 2020 17:31:23

FDA-CBER-2022-1614-1778924

US3472001
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 17:42:27
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:40:02
User entered 'No (N)'	Jie Ho (b) (4)	31 Aug 2020 17:31:23

FDA-CBER-2022-1614-1778925

US3472001
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 17:42:27
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:40:02
User entered empty.	Jie Ho (b) (4)	31 Aug 2020 17:31:23

FDA-CBER-2022-1614-1778926

US3472001
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 17:42:27
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered empty.	System	31 Aug 2020 17:31:23

FDA-CBER-2022-1614-1778927

US3472001
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 09 Jun 2021 17:42:27
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 18:51:55
User entered 'Yes (Y)'	Jie Ho (b) (4)	31 Aug 2020 17:32:09

FDA-CBER-2022-1614-1778928

US3472001
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 09 Jun 2021 17:42:27
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered '1'	System	31 Aug 2020 17:32:09

FDA-CBER-2022-1614-1778929

US3472001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 17:42:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
Data entry locked.	System	31 Aug 2020 15:27:47
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Aug 2020 15:27:47

FDA-CBER-2022-1614-1778930

US3472001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 17:42:27
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24

FDA-CBER-2022-1614-1778931

US3472001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 17:42:27
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24

FDA-CBER-2022-1614-1778932

US3472001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 17:42:27
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24

FDA-CBER-2022-1614-1778933

US3472001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 17:42:27
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24

FDA-CBER-2022-1614-1778934

US3472001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 17:42:27
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24

FDA-CBER-2022-1614-1778935

US3472001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 17:42:27
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24

FDA-CBER-2022-1614-1778936

US3472001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 17:42:27
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
User entered '31 Aug 2020 11:41'	System	31 Aug 2020 15:27:47

FDA-CBER-2022-1614-1778937

US3472001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 17:42:27
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
User entered '31 Aug 2020 14:11'	System	31 Aug 2020 15:27:47

FDA-CBER-2022-1614-1778938

US3472001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 17:42:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
Data entry locked.	System	31 Aug 2020 15:27:47
User entered 'Day 1, after vaccination (at home)'	System	31 Aug 2020 15:27:47

FDA-CBER-2022-1614-1778939

US3472001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 17:42:27
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-08-31T21:22:48', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'afb83082-23f0-4aa6-95b6-1eeb6b698e77'	System	01 Sep 2020 01:23:47
User entered 'Yes (Y)'	System	01 Sep 2020 01:23:47

FDA-CBER-2022-1614-1778940

US3472001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 17:42:27
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-08-31T21:23:13', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'afb83082-23f0-4aa6-95b6-1eeb6b698e77'	(b) (4), (b) (6) System	01 Sep 2020 01:23:47
User entered '97.6'	System	01 Sep 2020 01:23:47

FDA-CBER-2022-1614-1778941

US3472001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 17:42:27
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-08-31T21:23:18', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'afb83082-23f0-4aa6-95b6-1eeb6b698e77'	(b) (4), (b) (6) System	01 Sep 2020 01:23:47
User entered 'No (N)'	System	01 Sep 2020 01:23:47

FDA-CBER-2022-1614-1778942

US3472001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 17:42:27
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-08-31T21:23:43', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'afb83082-23f0-4aa6-95b6-1eeb6b698e77'	System	01 Sep 2020 01:23:47
User entered '31 Aug 2020 21:23'	System	01 Sep 2020 01:23:47

FDA-CBER-2022-1614-1778943

US3472001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 17:42:27
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
User entered '31 Aug 2020 15:06'	(b) (4), (b) (6) System	31 Aug 2020 15:27:47

FDA-CBER-2022-1614-1778944

US3472001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 17:42:27
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
User entered '01 Sep 2020 11:59'	(b) (4), (b) (6) System	31 Aug 2020 15:27:47

FDA-CBER-2022-1614-1778945

US3472001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 17:42:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
Data entry locked.	System	31 Aug 2020 15:27:47
User entered 'Day 2'	System	31 Aug 2020 15:27:47

FDA-CBER-2022-1614-1778946

US3472001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 17:42:27
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-01T16:09:32', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'c4bf53cd-e0ba-4f0c-abf7-671380eb8793'	(b) (4), (b) (6) System	01 Sep 2020 20:09:57
User entered 'Yes (Y)'	System	01 Sep 2020 20:09:57

FDA-CBER-2022-1614-1778947

US3472001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 17:42:27
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-01T16:09:42', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'c4bf53cd-e0ba-4f0c-abf7-671380eb8793'	(b) (4), (b) (6) System	01 Sep 2020 20:09:57
User entered '98.6'	System	01 Sep 2020 20:09:57

FDA-CBER-2022-1614-1778948

US3472001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 17:42:27
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-01T16:09:47', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'c4bf53cd-e0ba-4f0c-abf7-671380eb8793'	(b) (4), (b) (6) System	01 Sep 2020 20:09:57
User entered 'No (N)'	System	01 Sep 2020 20:09:57

FDA-CBER-2022-1614-1778949

US3472001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 17:42:27
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-01T16:09:54', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'c4bf53cd-e0ba-4f0c-abf7-671380eb8793'	System	01 Sep 2020 20:09:57
User entered '01 Sep 2020 16:09'	System	01 Sep 2020 20:09:57

FDA-CBER-2022-1614-1778950

US3472001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 17:42:27
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
User entered '01 Sep 2020 12:00'	(b) (4), (b) (6) System	31 Aug 2020 15:27:47

FDA-CBER-2022-1614-1778951

US3472001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 17:42:27
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
User entered '02 Sep 2020 11:59'	(b) (4), (b) (6) System	31 Aug 2020 15:27:47

FDA-CBER-2022-1614-1778952

US3472001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:42:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
Data entry locked.	System	31 Aug 2020 15:27:47
User entered 'Day 3'	System	31 Aug 2020 15:27:47

FDA-CBER-2022-1614-1778953

US3472001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:42:27
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-02T19:29:09', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'a1bfe350-3513-4b2a-8a78-bc7372619879'	(b) (4), (b) (6) System	02 Sep 2020 23:29:30
User entered 'Yes (Y)'	System	02 Sep 2020 23:29:30

FDA-CBER-2022-1614-1778954

US3472001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:42:27
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-02T19:29:16', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'a1bfe350-3513-4b2a-8a78-bc7372619879'	System	02 Sep 2020 23:29:30
User entered '98.1'	System	02 Sep 2020 23:29:30

FDA-CBER-2022-1614-1778955

US3472001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:42:27
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-02T19:29:20', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'a1bfe350-3513-4b2a-8a78-bc7372619879'	(b) (4), (b) (6) System	02 Sep 2020 23:29:30
User entered 'No (N)'	System	02 Sep 2020 23:29:30

FDA-CBER-2022-1614-1778956

US3472001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:42:27
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-02T19:29:27', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'a1bfe350-3513-4b2a-8a78-bc7372619879'	(b) (4), (b) (6) System	02 Sep 2020 23:29:30
User entered '02 Sep 2020 19:29'	System	02 Sep 2020 23:29:30

FDA-CBER-2022-1614-1778957

US3472001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:42:27
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
User entered '02 Sep 2020 12:00'	(b) (4), (b) (6) System	31 Aug 2020 15:27:47

FDA-CBER-2022-1614-1778958

US3472001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:42:27
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
User entered '03 Sep 2020 11:59'	(b) (4), (b) (6) System	31 Aug 2020 15:27:47

FDA-CBER-2022-1614-1778959

US3472001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:42:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
Data entry locked.	System	31 Aug 2020 15:27:47
User entered 'Day 4'	System	31 Aug 2020 15:27:47

FDA-CBER-2022-1614-1778960

US3472001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:42:27
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-03T23:20:20', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '7f21ca40-bd50-457d-9f1b-f40467c0c0a8'	(b) (4), (b) (6) System	04 Sep 2020 03:20:41
User entered 'Yes (Y)'	System	04 Sep 2020 03:20:41

FDA-CBER-2022-1614-1778961

US3472001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:42:27
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-03T23:20:28', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '7f21ca40-bd50-457d-9f1b-f40467c0c0a8'	System	04 Sep 2020 03:20:41
User entered '97.4'	System	04 Sep 2020 03:20:41

FDA-CBER-2022-1614-1778962

US3472001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:42:27
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-03T23:20:32', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '7f21ca40-bd50-457d-9f1b-f40467c0c0a8'	(b) (4), (b) (6) System	04 Sep 2020 03:20:41
User entered 'No (N)'	System	04 Sep 2020 03:20:41

FDA-CBER-2022-1614-1778963

US3472001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:42:27
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-03T23:20:40', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '7f21ca40-bd50-457d-9f1b-f40467c0c0a8'	System	04 Sep 2020 03:20:41
User entered '03 Sep 2020 23:20'	System	04 Sep 2020 03:20:41

FDA-CBER-2022-1614-1778964

US3472001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:42:27
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
User entered '03 Sep 2020 12:00'	(b) (4), (b) (6) System	31 Aug 2020 15:27:47

FDA-CBER-2022-1614-1778965

US3472001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:42:27
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
User entered '04 Sep 2020 11:59'	(b) (4), (b) (6) System	31 Aug 2020 15:27:47

FDA-CBER-2022-1614-1778966

US3472001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 17:42:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
Data entry locked.	System	31 Aug 2020 15:27:47
User entered 'Day 5'	System	31 Aug 2020 15:27:47

FDA-CBER-2022-1614-1778967

US3472001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 17:42:27
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-04T23:59:46', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '74727a0d-2cc1-480c-b5d2-c4091d4814dd'	(b) (4), (b) (6) System	05 Sep 2020 04:00:37
User entered 'Yes (Y)'	System	05 Sep 2020 04:00:37

FDA-CBER-2022-1614-1778968

US3472001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 17:42:27
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-05T00:00:16', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '74727a0d-2cc1-480c-b5d2-c4091d4814dd'	System	05 Sep 2020 04:00:37
User entered '98.3'	System	05 Sep 2020 04:00:37

FDA-CBER-2022-1614-1778969

US3472001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 17:42:27
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-05T00:00:19', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '74727a0d-2cc1-480c-b5d2-c4091d4814dd'	(b) (4), (b) (6) System	05 Sep 2020 04:00:37
User entered 'No (N)'	System	05 Sep 2020 04:00:37

FDA-CBER-2022-1614-1778970

US3472001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 17:42:27
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-05T00:00:31', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '74727a0d-2cc1-480c-b5d2-c4091d4814dd'	(b) (4), (b) (6) System	05 Sep 2020 04:00:37
User entered '05 Sep 2020 00:00'	System	05 Sep 2020 04:00:37

FDA-CBER-2022-1614-1778971

US3472001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 17:42:27
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
User entered '04 Sep 2020 12:00'	(b) (4), (b) (6) System	31 Aug 2020 15:27:47

FDA-CBER-2022-1614-1778972

US3472001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 17:42:27
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
User entered '05 Sep 2020 11:59'	(b) (4), (b) (6) System	31 Aug 2020 15:27:47

FDA-CBER-2022-1614-1778973

US3472001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:42:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
Data entry locked.	System	31 Aug 2020 15:27:47
User entered 'Day 6'	System	31 Aug 2020 15:27:47

FDA-CBER-2022-1614-1778974

US3472001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:42:27
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-05T19:09:10', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'a805f68c-1a4b-4650-8276-82484855c5de'	(b) (4), (b) (6) System	05 Sep 2020 23:09:30
User entered 'Yes (Y)'	System	05 Sep 2020 23:09:30

FDA-CBER-2022-1614-1778975

US3472001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:42:27
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-05T19:09:16', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'a805f68c-1a4b-4650-8276-82484855c5de'	(b) (4), (b) (6) System	05 Sep 2020 23:09:30
User entered '97.7'	System	05 Sep 2020 23:09:30

FDA-CBER-2022-1614-1778976

US3472001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:42:27
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-05T19:09:19', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'a805f68c-1a4b-4650-8276-82484855c5de'	(b) (4), (b) (6) System	05 Sep 2020 23:09:30
User entered 'No (N)'	System	05 Sep 2020 23:09:30

FDA-CBER-2022-1614-1778977

US3472001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:42:27
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-05T19:09:28', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'a805f68c-1a4b-4650-8276-82484855c5de'	(b) (4), (b) (6) System	05 Sep 2020 23:09:30
User entered '05 Sep 2020 19:09'	System	05 Sep 2020 23:09:30

FDA-CBER-2022-1614-1778978

US3472001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:42:27
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
User entered '05 Sep 2020 12:00'	(b) (4), (b) (6) System	31 Aug 2020 15:27:47

FDA-CBER-2022-1614-1778979

US3472001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:42:27
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
User entered '06 Sep 2020 11:59'	(b) (4), (b) (6) System	31 Aug 2020 15:27:47

FDA-CBER-2022-1614-1778980

US3472001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 17:42:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
Data entry locked.	System	31 Aug 2020 15:27:47
User entered 'Day 7'	System	31 Aug 2020 15:27:47

FDA-CBER-2022-1614-1778981

US3472001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 17:42:27
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-06T17:44:04', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '48771f2f-3575-4d5d-8295-c717e4125d98'	(b) (4), (b) (6) System	06 Sep 2020 21:44:30
User entered 'Yes (Y)'	System	06 Sep 2020 21:44:30

FDA-CBER-2022-1614-1778982

US3472001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 17:42:27
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-06T17:44:15', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '48771f2f-3575-4d5d-8295-c717e4125d98'	(b) (4), (b) (6) System	06 Sep 2020 21:44:30
User entered '97.7'	System	06 Sep 2020 21:44:30

FDA-CBER-2022-1614-1778983

US3472001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 17:42:27
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-06T17:44:20', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '48771f2f-3575-4d5d-8295-c717e4125d98'	(b) (4), (b) (6) System	06 Sep 2020 21:44:30
User entered 'No (N)'	System	06 Sep 2020 21:44:30

FDA-CBER-2022-1614-1778984

US3472001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 17:42:27
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-06T17:44:27', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '48771f2f-3575-4d5d-8295-c717e4125d98'	(b) (4), (b) (6) System	06 Sep 2020 21:44:30
User entered '06 Sep 2020 17:44'	System	06 Sep 2020 21:44:30

FDA-CBER-2022-1614-1778985

US3472001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 17:42:27
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
User entered '06 Sep 2020 12:00'	(b) (4), (b) (6) System	31 Aug 2020 15:27:47

FDA-CBER-2022-1614-1778986

US3472001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 17:42:27
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
User entered '07 Sep 2020 11:59'	(b) (4), (b) (6) System	31 Aug 2020 15:27:47

FDA-CBER-2022-1614-1778987

US3472001
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:42:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
Data entry locked.	System	31 Aug 2020 15:27:47
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Aug 2020 15:27:47

FDA-CBER-2022-1614-1778988

US3472001
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:42:27
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 01:17:24

FDA-CBER-2022-1614-1778989

US3472001
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:42:27
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 01:17:24

FDA-CBER-2022-1614-1778990

US3472001
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:42:27
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) (b) (4), (b) (6)	26 Feb 2021 01:17:24

FDA-CBER-2022-1614-1778991

US3472001
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:42:27
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 01:17:24

FDA-CBER-2022-1614-1778992

US3472001
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:42:27
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) (b) (4), (b) (6)	26 Feb 2021 01:17:24

FDA-CBER-2022-1614-1778993

US3472001
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:42:27
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 01:17:24

FDA-CBER-2022-1614-1778994

US3472001
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:42:27
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Feb 2021 01:17:24

FDA-CBER-2022-1614-1778995

US3472001
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:42:27
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
User entered '31 Aug 2020 11:41'	(b) (4), (b) (6) System	31 Aug 2020 15:27:47

FDA-CBER-2022-1614-1778996

US3472001
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:42:27
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
User entered '31 Aug 2020 14:11'	(b) (4), (b) (6) System	31 Aug 2020 15:27:47

FDA-CBER-2022-1614-1778997

US3472001
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:42:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
Data entry locked.	System	31 Aug 2020 15:27:47
User entered 'Day 1, after vaccination (at home)'	System	31 Aug 2020 15:27:47

FDA-CBER-2022-1614-1778998

US3472001
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:42:27
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 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-08-31T21:23:54', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '1a17a392-db53-4e76-8b08-a78461604d9b'	(b) (4), (b) (6) System	01 Sep 2020 01:24:13
User entered 'None (1)'	System	01 Sep 2020 01:24:13

FDA-CBER-2022-1614-1778999

US3472001
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:42:27
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-08-31T21:23:57', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '1a17a392-db53-4e76-8b08-a78461604d9b'	(b) (4), (b) (6) System	01 Sep 2020 01:24:13
User entered 'No (N)'	System	01 Sep 2020 01:24:13

FDA-CBER-2022-1614-1779000

US3472001
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:42:27
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-08-31T21:24:01', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '1a17a392-db53-4e76-8b08-a78461604d9b'	(b) (4), (b) (6) System	01 Sep 2020 01:24:13
User entered 'No (N)'	System	01 Sep 2020 01:24:13

FDA-CBER-2022-1614-1779001

US3472001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:42:27

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 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-08-31T21:24:06', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '1a17a392-db53-4e76-8b08-a78461604d9b'	(b) (4), (b) (6) System	01 Sep 2020 01:24:13
User entered 'None (1)'	System	01 Sep 2020 01:24:13

US3472001
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:42:27
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-08-31T21:24:12', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '1a17a392-db53-4e76-8b08-a78461604d9b'	System	01 Sep 2020 01:24:13
User entered '31 Aug 2020 21:24'	System	01 Sep 2020 01:24:13

FDA-CBER-2022-1614-1779003

US3472001
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:42:27
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
User entered '31 Aug 2020 15:06'	(b) (4), (b) (6) System	31 Aug 2020 15:27:47

FDA-CBER-2022-1614-1779004

US3472001
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:42:27
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
User entered '01 Sep 2020 11:59'	(b) (4), (b) (6) System	31 Aug 2020 15:27:47

FDA-CBER-2022-1614-1779005

US3472001
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:42:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
Data entry locked.	System	31 Aug 2020 15:27:47
User entered 'Day 2'	System	31 Aug 2020 15:27:47

FDA-CBER-2022-1614-1779006

US3472001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:42:27

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 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-01T16:10:13', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '553d754d-aae1-48bf-b26a-5a27f2ce94d7'	(b) (4), (b) (6) System	01 Sep 2020 20:10:34
User entered 'None (1)'	System	01 Sep 2020 20:10:34

US3472001
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:42:27
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-01T16:10:17', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '553d754d-aae1-48bf-b26a-5a27f2ce94d7'	System	01 Sep 2020 20:10:34
User entered 'No (N)'	System	01 Sep 2020 20:10:34

FDA-CBER-2022-1614-1779008

US3472001
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:42:27
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-01T16:10:21', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '553d754d-aae1-48bf-b26a-5a27f2ce94d7'	(b) (4), (b) (6) System	01 Sep 2020 20:10:34
User entered 'No (N)'	System	01 Sep 2020 20:10:34

FDA-CBER-2022-1614-1779009

US3472001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:42:27

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 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-01T16:10:27', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '553d754d-aae1-48bf-b26a-5a27f2ce94d7'	(b) (4), (b) (6) System	01 Sep 2020 20:10:34
User entered 'None (1)'	System	01 Sep 2020 20:10:34

US3472001
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:42:27
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-01T16:10:31', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '553d754d-aae1-48bf-b26a-5a27f2ce94d7'	System	01 Sep 2020 20:10:34
User entered '01 Sep 2020 16:10'	System	01 Sep 2020 20:10:34

FDA-CBER-2022-1614-1779011

US3472001
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:42:27
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
User entered '01 Sep 2020 12:00'	(b) (4), (b) (6) System	31 Aug 2020 15:27:47

FDA-CBER-2022-1614-1779012

US3472001
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:42:27
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
User entered '02 Sep 2020 11:59'	(b) (4), (b) (6) System	31 Aug 2020 15:27:47

FDA-CBER-2022-1614-1779013

US3472001
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:42:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
Data entry locked.	System	31 Aug 2020 15:27:47
User entered 'Day 3'	System	31 Aug 2020 15:27:47

FDA-CBER-2022-1614-1779014

US3472001
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:42:27
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 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-02T19:29:36', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '4626c397-a956-4f82-9e3a-f5d7332a3972'	(b) (4), (b) (6) System	02 Sep 2020 23:29:56
User entered 'None (1)'	System	02 Sep 2020 23:29:56

FDA-CBER-2022-1614-1779015

US3472001
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:42:27
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-02T19:29:40', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '4626c397-a956-4f82-9e3a-f5d7332a3972'	(b) (4), (b) (6) System	02 Sep 2020 23:29:56
User entered 'No (N)'	System	02 Sep 2020 23:29:56

FDA-CBER-2022-1614-1779016

US3472001
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:42:27
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-02T19:29:43', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '4626c397-a956-4f82-9e3a-f5d7332a3972'	(b) (4), (b) (6) System	02 Sep 2020 23:29:56
User entered 'No (N)'	System	02 Sep 2020 23:29:56

FDA-CBER-2022-1614-1779017

US3472001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:42:27

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 01:17:24
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-02T19:29:49', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '4626c397-a956-4f82-9e3a-f5d7332a3972'	System	02 Sep 2020 23:29:56
User entered 'None (1)'	System	02 Sep 2020 23:29:56

US3472001
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:42:27
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-02T19:29:52', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '4626c397-a956-4f82-9e3a-f5d7332a3972'	System	02 Sep 2020 23:29:56
User entered '02 Sep 2020 19:29'	System	02 Sep 2020 23:29:56

FDA-CBER-2022-1614-1779019

US3472001
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:42:27
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
User entered '02 Sep 2020 12:00'	(b) (4), (b) (6) System	31 Aug 2020 15:27:47

FDA-CBER-2022-1614-1779020

US3472001
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:42:27
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
User entered '03 Sep 2020 11:59'	(b) (4), (b) (6) System	31 Aug 2020 15:27:47

FDA-CBER-2022-1614-1779021

US3472001
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:42:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
Data entry locked.	System	31 Aug 2020 15:27:47
User entered 'Day 4'	System	31 Aug 2020 15:27:47

FDA-CBER-2022-1614-1779022

US3472001
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:42:27
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 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-03T23:21:00', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'fb6f1136-056f-4f8b-bf57-bdb27306c85f'	(b) (4), (b) (6) System	04 Sep 2020 03:21:17
User entered 'None (1)'	System	04 Sep 2020 03:21:17

US3472001
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:42:27
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-03T23:20:58', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'fb6f1136-056f-4f8b-bf57-bdb27306c85f'	(b) (4), (b) (6) System	04 Sep 2020 03:21:17
User entered 'No (N)'	System	04 Sep 2020 03:21:17

FDA-CBER-2022-1614-1779024

US3472001
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:42:27
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-03T23:21:04', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'fb6f1136-056f-4f8b-bf57-bdb27306c85f'	(b) (4), (b) (6) System	04 Sep 2020 03:21:17
User entered 'No (N)'	System	04 Sep 2020 03:21:17

FDA-CBER-2022-1614-1779025

US3472001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:42:27

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 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-03T23:21:10', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'fb6f1136-056f-4f8b-bf57-bdb27306c85f'	(b) (4), (b) (6) System	04 Sep 2020 03:21:17
User entered 'None (1)'	System	04 Sep 2020 03:21:17

US3472001
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:42:27
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-03T23:21:15', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'fb6f1136-056f-4f8b-bf57-bdb27306c85f'	System	04 Sep 2020 03:21:17
User entered '03 Sep 2020 23:21'	System	04 Sep 2020 03:21:17

FDA-CBER-2022-1614-1779027

US3472001
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:42:27
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
User entered '03 Sep 2020 12:00'	(b) (4), (b) (6) System	31 Aug 2020 15:27:47

FDA-CBER-2022-1614-1779028

US3472001
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:42:27
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
User entered '04 Sep 2020 11:59'	(b) (4), (b) (6) System	31 Aug 2020 15:27:47

FDA-CBER-2022-1614-1779029

US3472001
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:42:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
Data entry locked.	System	31 Aug 2020 15:27:47
User entered 'Day 5'	System	31 Aug 2020 15:27:47

FDA-CBER-2022-1614-1779030

US3472001
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:42:27
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 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-05T00:00:35', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '525fed39-7410-4918-8229-ecbcf153b61e'	(b) (4), (b) (6) System	05 Sep 2020 04:00:54
User entered 'None (1)'	System	05 Sep 2020 04:00:54

US3472001
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:42:27
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-05T00:00:40', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '525fed39-7410-4918-8229-ecbcf153b61e'	(b) (4), (b) (6) System	05 Sep 2020 04:00:54
User entered 'No (N)'	System	05 Sep 2020 04:00:54

FDA-CBER-2022-1614-1779032

US3472001
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:42:27
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-05T00:00:43', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '525fed39-7410-4918-8229-ecbcf153b61e'	(b) (4), (b) (6) System	05 Sep 2020 04:00:54
User entered 'No (N)'	System	05 Sep 2020 04:00:54

FDA-CBER-2022-1614-1779033

US3472001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:42:27

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 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-05T00:00:45', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '525fed39-7410-4918-8229-ecbcf153b61e'	(b) (4), (b) (6) System	05 Sep 2020 04:00:54
User entered 'None (1)'	System	05 Sep 2020 04:00:54

US3472001
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:42:27
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-05T00:00:50', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '525fed39-7410-4918-8229-ecbcf153b61e'	(b) (4), (b) (6) System	05 Sep 2020 04:00:54
User entered '05 Sep 2020 00:00'	System	05 Sep 2020 04:00:54

FDA-CBER-2022-1614-1779035

US3472001
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:42:27
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
User entered '04 Sep 2020 12:00'	(b) (4), (b) (6) System	31 Aug 2020 15:27:47

FDA-CBER-2022-1614-1779036

US3472001
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:42:27
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
User entered '05 Sep 2020 11:59'	(b) (4), (b) (6) System	31 Aug 2020 15:27:47

FDA-CBER-2022-1614-1779037

US3472001
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:42:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
Data entry locked.	System	31 Aug 2020 15:27:47
User entered 'Day 6'	System	31 Aug 2020 15:27:47

FDA-CBER-2022-1614-1779038

US3472001
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:42:27
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 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-05T19:09:33', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '270de8a8-c94d-4faf-bfc9-15b115db7be4'	(b) (4), (b) (6) System	05 Sep 2020 23:10:02
User entered 'None (1)'	System	05 Sep 2020 23:10:02

FDA-CBER-2022-1614-1779039

US3472001
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:42:27
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-05T19:09:38', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '270de8a8-c94d-4faf-bfc9-15b115db7be4'	(b) (4), (b) (6) System	05 Sep 2020 23:10:02
User entered 'No (N)'	System	05 Sep 2020 23:10:02

FDA-CBER-2022-1614-1779040

US3472001
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:42:27
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-05T19:09:40', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '270de8a8-c94d-4faf-bfc9-15b115db7be4'	(b) (4), (b) (6) System	05 Sep 2020 23:10:02
User entered 'No (N)'	System	05 Sep 2020 23:10:02

FDA-CBER-2022-1614-1779041

US3472001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:42:27

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 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-05T19:09:46', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '270de8a8-c94d-4faf-bfc9-15b115db7be4'	(b) (4), (b) (6) System	05 Sep 2020 23:10:02
User entered 'None (1)'	System	05 Sep 2020 23:10:02

US3472001
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:42:27
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-05T19:09:57', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '270de8a8-c94d-4faf-bfc9-15b115db7be4'	(b) (4), (b) (6) System	05 Sep 2020 23:10:02
User entered '05 Sep 2020 19:09'	System	05 Sep 2020 23:10:02

FDA-CBER-2022-1614-1779043

US3472001
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:42:27
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
User entered '05 Sep 2020 12:00'	(b) (4), (b) (6) System	31 Aug 2020 15:27:47

FDA-CBER-2022-1614-1779044

US3472001
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:42:27
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
User entered '06 Sep 2020 11:59'	(b) (4), (b) (6) System	31 Aug 2020 15:27:47

FDA-CBER-2022-1614-1779045

US3472001
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:42:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
Data entry locked.	System	31 Aug 2020 15:27:47
User entered 'Day 7'	System	31 Aug 2020 15:27:47

FDA-CBER-2022-1614-1779046

US3472001
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:42:27
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 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-06T17:44:32', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '7dc36edd-5109-47d1-9bcf-bf4b60f1148d'	(b) (4), (b) (6) System	06 Sep 2020 21:44:50
User entered 'None (1)'	System	06 Sep 2020 21:44:50

US3472001
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:42:27
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-06T17:44:35', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '7dc36edd-5109-47d1-9bcf-bf4b60f1148d'	(b) (4), (b) (6) System	06 Sep 2020 21:44:50
User entered 'No (N)'	System	06 Sep 2020 21:44:50

FDA-CBER-2022-1614-1779048

US3472001
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:42:27
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-06T17:44:38', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '7dc36edd-5109-47d1-9bcf-bf4b60f1148d'	(b) (4), (b) (6) System	06 Sep 2020 21:44:50
User entered 'No (N)'	System	06 Sep 2020 21:44:50

FDA-CBER-2022-1614-1779049

US3472001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:42:27

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 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-06T17:44:43', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '7dc36edd-5109-47d1-9bcf-bf4b60f1148d'	(b) (4), (b) (6) System	06 Sep 2020 21:44:50
User entered 'None (1)'	System	06 Sep 2020 21:44:50

US3472001
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:42:27
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-06T17:44:47', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '7dc36edd-5109-47d1-9bcf-bf4b60f1148d'	(b) (4), (b) (6) System	06 Sep 2020 21:44:50
User entered '06 Sep 2020 17:44'	System	06 Sep 2020 21:44:50

FDA-CBER-2022-1614-1779051

US3472001
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:42:27
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
User entered '06 Sep 2020 12:00'	(b) (4), (b) (6) System	31 Aug 2020 15:27:47

FDA-CBER-2022-1614-1779052

US3472001
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:42:27
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
User entered '07 Sep 2020 11:59'	(b) (4), (b) (6) System	31 Aug 2020 15:27:47

FDA-CBER-2022-1614-1779053

US3472001
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:42:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
Data entry locked.	System	31 Aug 2020 15:27:47
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Aug 2020 15:27:47

FDA-CBER-2022-1614-1779054

US3472001
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:42:27
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-08-31T11:55:20', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'de5014c6-d77a-4410-9f52-7c29c5f1c9a6'	(b) (4), (b) (6) System	31 Aug 2020 15:57:30
User entered 'None (0)'	System	31 Aug 2020 15:57:30

FDA-CBER-2022-1614-1779055

US3472001
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:42:27
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-08-31T11:55:28', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'de5014c6-d77a-4410-9f52-7c29c5f1c9a6'	(b) (4), (b) (6) System	31 Aug 2020 15:57:30
User entered 'None (0)'	System	31 Aug 2020 15:57:30

FDA-CBER-2022-1614-1779056

US3472001
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:42:27
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-08-31T11:55:31', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'de5014c6-d77a-4410-9f52-7c29c5f1c9a6'	(b) (4), (b) (6) System	31 Aug 2020 15:57:30
User entered 'None (0)'	System	31 Aug 2020 15:57:30

FDA-CBER-2022-1614-1779057

US3472001
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:42:27
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-08-31T11:55:34', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'de5014c6-d77a-4410-9f52-7c29c5f1c9a6'	(b) (4), (b) (6) System	31 Aug 2020 15:57:30
User entered 'None (0)'	System	31 Aug 2020 15:57:30

FDA-CBER-2022-1614-1779058

US3472001
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:42:27
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-08-31T11:55:36', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'de5014c6-d77a-4410-9f52-7c29c5f1c9a6'	System	31 Aug 2020 15:57:30
User entered 'None (0)'	System	31 Aug 2020 15:57:30

FDA-CBER-2022-1614-1779059

US3472001
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:42:27
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-08-31T11:55:38', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'de5014c6-d77a-4410-9f52-7c29c5f1c9a6'	System	31 Aug 2020 15:57:30
User entered 'None (0)'	System	31 Aug 2020 15:57:30

FDA-CBER-2022-1614-1779060

US3472001
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:42:27
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 01:17:24
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-08-31T11:55:46', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'de5014c6-d77a-4410-9f52-7c29c5f1c9a6'	System	31 Aug 2020 15:57:30
User entered 'No (N)'	System	31 Aug 2020 15:57:30

FDA-CBER-2022-1614-1779061

US3472001
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:42:27
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-08-31T11:55:56', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'de5014c6-d77a-4410-9f52-7c29c5f1c9a6'	System	31 Aug 2020 15:57:30
User entered '31 Aug 2020 11:55'	System	31 Aug 2020 15:57:30

FDA-CBER-2022-1614-1779062

US3472001
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:42:27
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
User entered '31 Aug 2020 11:41'	(b) (4), (b) (6) System	31 Aug 2020 15:27:47

FDA-CBER-2022-1614-1779063

US3472001
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:42:27
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
User entered '31 Aug 2020 14:11'	(b) (4), (b) (6) System	31 Aug 2020 15:27:47

FDA-CBER-2022-1614-1779064

US3472001
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:42:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
Data entry locked.	System	31 Aug 2020 15:27:47
User entered 'Day 1, after vaccination (at home)'	System	31 Aug 2020 15:27:47

FDA-CBER-2022-1614-1779065

US3472001
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:42:27
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-01T06:47:58', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'd538e4ad-92f6-4bfb-a2f7-27650285fa9b'	(b) (4), (b) (6) System	01 Sep 2020 10:48:28
User entered 'None (0)'	System	01 Sep 2020 10:48:28

FDA-CBER-2022-1614-1779066

US3472001
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:42:27
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-01T06:48:02', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'd538e4ad-92f6-4bfb-a2f7-27650285fa9b'	(b) (4), (b) (6) System	01 Sep 2020 10:48:28
User entered 'None (0)'	System	01 Sep 2020 10:48:28

FDA-CBER-2022-1614-1779067

US3472001
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:42:27
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-01T06:48:05', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'd538e4ad-92f6-4bfb-a2f7-27650285fa9b'	(b) (4), (b) (6) System	01 Sep 2020 10:48:28
User entered 'None (0)'	System	01 Sep 2020 10:48:28

FDA-CBER-2022-1614-1779068

US3472001
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:42:27
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-01T06:48:08', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'd538e4ad-92f6-4bfb-a2f7-27650285fa9b'	System	01 Sep 2020 10:48:28
User entered 'None (0)'	System	01 Sep 2020 10:48:28

FDA-CBER-2022-1614-1779069

US3472001
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:42:27
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-01T06:48:11', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'd538e4ad-92f6-4bfb-a2f7-27650285fa9b'	(b) (4), (b) (6) System	01 Sep 2020 10:48:28
User entered 'None (0)'	System	01 Sep 2020 10:48:28

FDA-CBER-2022-1614-1779070

US3472001
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:42:27
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-01T06:48:14', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'd538e4ad-92f6-4bfb-a2f7-27650285fa9b'	(b) (4), (b) (6) System	01 Sep 2020 10:48:28
User entered 'None (0)'	System	01 Sep 2020 10:48:28

FDA-CBER-2022-1614-1779071

US3472001
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:42:27
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 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-01T06:48:21', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'd538e4ad-92f6-4bfb-a2f7-27650285fa9b'	(b) (4), (b) (6) System	01 Sep 2020 10:48:28
User entered 'No (N)'	System	01 Sep 2020 10:48:28

FDA-CBER-2022-1614-1779072

US3472001
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:42:27
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-01T06:48:26', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'd538e4ad-92f6-4bfb-a2f7-27650285fa9b'	System	01 Sep 2020 10:48:28
User entered '01 Sep 2020 06:48'	System	01 Sep 2020 10:48:28

FDA-CBER-2022-1614-1779073

US3472001
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:42:27
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
User entered '31 Aug 2020 15:06'	(b) (4), (b) (6) System	31 Aug 2020 15:27:47

FDA-CBER-2022-1614-1779074

US3472001
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:42:27
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
User entered '01 Sep 2020 11:59'	(b) (4), (b) (6) System	31 Aug 2020 15:27:47

FDA-CBER-2022-1614-1779075

US3472001
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:42:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
Data entry locked.	System	31 Aug 2020 15:27:47
User entered 'Day 2'	System	31 Aug 2020 15:27:47

FDA-CBER-2022-1614-1779076

US3472001
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:42:27
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-01T16:10:37', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '0e593b1e-6080-4b65-a814-bb20310ab0e7'	(b) (4), (b) (6) System	01 Sep 2020 20:10:58
User entered 'None (0)'	System	01 Sep 2020 20:10:58

FDA-CBER-2022-1614-1779077

US3472001
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:42:27
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-01T16:10:39', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '0e593b1e-6080-4b65-a814-bb20310ab0e7'	(b) (4), (b) (6) System	01 Sep 2020 20:10:58
User entered 'None (0)'	System	01 Sep 2020 20:10:58

FDA-CBER-2022-1614-1779078

US3472001
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:42:27
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-01T16:10:41', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '0e593b1e-6080-4b65-a814-bb20310ab0e7'	System	01 Sep 2020 20:10:58
User entered 'None (0)'	System	01 Sep 2020 20:10:58

FDA-CBER-2022-1614-1779079

US3472001
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:42:27
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-01T16:10:43', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '0e593b1e-6080-4b65-a814-bb20310ab0e7'	(b) (4), (b) (6) System	01 Sep 2020 20:10:58
User entered 'None (0)'	System	01 Sep 2020 20:10:58

FDA-CBER-2022-1614-1779080

US3472001
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:42:27
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-01T16:10:46', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '0e593b1e-6080-4b65-a814-bb20310ab0e7'	(b) (4), (b) (6) System	01 Sep 2020 20:10:58
User entered 'None (0)'	System	01 Sep 2020 20:10:58

FDA-CBER-2022-1614-1779081

US3472001
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:42:27
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-01T16:10:48', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '0e593b1e-6080-4b65-a814-bb20310ab0e7'	System	01 Sep 2020 20:10:58
User entered 'None (0)'	System	01 Sep 2020 20:10:58

FDA-CBER-2022-1614-1779082

US3472001
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:42:27
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 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-01T16:10:52', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '0e593b1e-6080-4b65-a814-bb20310ab0e7'	(b) (4), (b) (6) System	01 Sep 2020 20:10:58
User entered 'No (N)'	System	01 Sep 2020 20:10:58

FDA-CBER-2022-1614-1779083

US3472001
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:42:27
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-01T16:10:55', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '0e593b1e-6080-4b65-a814-bb20310ab0e7'	(b) (4), (b) (6) System	01 Sep 2020 20:10:58
User entered '01 Sep 2020 16:10'	System	01 Sep 2020 20:10:58

FDA-CBER-2022-1614-1779084

US3472001
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:42:27
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
User entered '01 Sep 2020 12:00'	(b) (4), (b) (6) System	31 Aug 2020 15:27:47

FDA-CBER-2022-1614-1779085

US3472001
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:42:27
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
User entered '02 Sep 2020 11:59'	(b) (4), (b) (6) System	31 Aug 2020 15:27:47

FDA-CBER-2022-1614-1779086

US3472001
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:42:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
Data entry locked.	System	31 Aug 2020 15:27:47
User entered 'Day 3'	System	31 Aug 2020 15:27:47

FDA-CBER-2022-1614-1779087

US3472001
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:42:27
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-02T19:29:57', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'e6eddfd5-fa1f-40b0-8b3c-4d1258743abb'	(b) (4), (b) (6) System	02 Sep 2020 23:30:20
User entered 'None (0)'	System	02 Sep 2020 23:30:20

FDA-CBER-2022-1614-1779088

US3472001
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:42:27
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-02T19:29:59', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'e6eddfd5-fa1f-40b0-8b3c-4d1258743abb'	System	02 Sep 2020 23:30:20
User entered 'None (0)'	System	02 Sep 2020 23:30:20

FDA-CBER-2022-1614-1779089

US3472001
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:42:27
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-02T19:30:01', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'e6eddfd5-fa1f-40b0-8b3c-4d1258743abb'	(b) (4), (b) (6) System	02 Sep 2020 23:30:20
User entered 'None (0)'	System	02 Sep 2020 23:30:20

FDA-CBER-2022-1614-1779090

US3472001
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:42:27
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-02T19:30:02', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'e6eddfd5-fa1f-40b0-8b3c-4d1258743abb'	System	02 Sep 2020 23:30:20
User entered 'None (0)'	System	02 Sep 2020 23:30:20

FDA-CBER-2022-1614-1779091

US3472001
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:42:27
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-02T19:30:04', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'e6eddfd5-fa1f-40b0-8b3c-4d1258743abb'	(b) (4), (b) (6) System	02 Sep 2020 23:30:20
User entered 'None (0)'	System	02 Sep 2020 23:30:20

FDA-CBER-2022-1614-1779092

US3472001
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:42:27
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-02T19:30:08', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'e6eddfd5-fa1f-40b0-8b3c-4d1258743abb'	(b) (4), (b) (6) System	02 Sep 2020 23:30:20
User entered 'None (0)'	System	02 Sep 2020 23:30:20

FDA-CBER-2022-1614-1779093

US3472001
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:42:27
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 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-02T19:30:13', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'e6eddfd5-fa1f-40b0-8b3c-4d1258743abb'	(b) (4), (b) (6) System	02 Sep 2020 23:30:20
User entered 'No (N)'	System	02 Sep 2020 23:30:20

FDA-CBER-2022-1614-1779094

US3472001
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:42:27
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-02T19:30:18', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'e6eddfd5-fa1f-40b0-8b3c-4d1258743abb'	(b) (4), (b) (6) System	02 Sep 2020 23:30:20
User entered '02 Sep 2020 19:30'	System	02 Sep 2020 23:30:20

FDA-CBER-2022-1614-1779095

US3472001
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:42:27
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
User entered '02 Sep 2020 12:00'	(b) (4), (b) (6) System	31 Aug 2020 15:27:47

FDA-CBER-2022-1614-1779096

US3472001
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:42:27
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
User entered '03 Sep 2020 11:59'	(b) (4), (b) (6) System	31 Aug 2020 15:27:47

FDA-CBER-2022-1614-1779097

US3472001
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:42:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
Data entry locked.	System	31 Aug 2020 15:27:47
User entered 'Day 4'	System	31 Aug 2020 15:27:47

FDA-CBER-2022-1614-1779098

US3472001
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:42:27
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-03T23:21:19', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'a431190d-8954-4e26-9c08-6af997ad85ab'	(b) (4), (b) (6) System	04 Sep 2020 03:21:40
User entered 'None (0)'	System	04 Sep 2020 03:21:40

FDA-CBER-2022-1614-1779099

US3472001
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:42:27
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-03T23:21:21', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'a431190d-8954-4e26-9c08-6af997ad85ab'	(b) (4), (b) (6) System	04 Sep 2020 03:21:40
User entered 'None (0)'	System	04 Sep 2020 03:21:40

FDA-CBER-2022-1614-1779100

US3472001
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:42:27
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-03T23:21:23', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'a431190d-8954-4e26-9c08-6af997ad85ab'	(b) (4), (b) (6) System	04 Sep 2020 03:21:40
User entered 'None (0)'	System	04 Sep 2020 03:21:40

FDA-CBER-2022-1614-1779101

US3472001
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:42:27
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-03T23:21:25', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'a431190d-8954-4e26-9c08-6af997ad85ab'	System	04 Sep 2020 03:21:40
User entered 'None (0)'	System	04 Sep 2020 03:21:40

FDA-CBER-2022-1614-1779102

US3472001
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:42:27
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-03T23:21:27', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'a431190d-8954-4e26-9c08-6af997ad85ab'	(b) (4), (b) (6) System	04 Sep 2020 03:21:40
User entered 'None (0)'	System	04 Sep 2020 03:21:40

FDA-CBER-2022-1614-1779103

US3472001
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:42:27
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-03T23:21:29', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'a431190d-8954-4e26-9c08-6af997ad85ab'	(b) (4), (b) (6) System	04 Sep 2020 03:21:40
User entered 'None (0)'	System	04 Sep 2020 03:21:40

FDA-CBER-2022-1614-1779104

US3472001
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:42:27
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 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-03T23:21:33', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'a431190d-8954-4e26-9c08-6af997ad85ab'	(b) (4), (b) (6) System	04 Sep 2020 03:21:40
User entered 'No (N)'	System	04 Sep 2020 03:21:40

FDA-CBER-2022-1614-1779105

US3472001
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:42:27
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-03T23:21:37', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'a431190d-8954-4e26-9c08-6af997ad85ab'	(b) (4), (b) (6) System	04 Sep 2020 03:21:40
User entered '03 Sep 2020 23:21'	System	04 Sep 2020 03:21:40

FDA-CBER-2022-1614-1779106

US3472001
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:42:27
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
User entered '03 Sep 2020 12:00'	(b) (4), (b) (6) System	31 Aug 2020 15:27:47

FDA-CBER-2022-1614-1779107

US3472001
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:42:27
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
User entered '04 Sep 2020 11:59'	(b) (4), (b) (6) System	31 Aug 2020 15:27:47

FDA-CBER-2022-1614-1779108

US3472001
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:42:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
Data entry locked.	System	31 Aug 2020 15:27:47
User entered 'Day 5'	System	31 Aug 2020 15:27:47

FDA-CBER-2022-1614-1779109

US3472001
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:42:27
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-05T00:00:54', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '8366d1a9-d067-4efe-aa3d-cdbbd93d72a5'	(b) (4), (b) (6) System	05 Sep 2020 04:01:21
User entered 'None (0)'	System	05 Sep 2020 04:01:21

FDA-CBER-2022-1614-1779110

US3472001
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:42:27
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-05T00:00:57', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '8366d1a9-d067-4efe-aa3d-cdbbd93d72a5'	(b) (4), (b) (6) System	05 Sep 2020 04:01:21
User entered 'None (0)'	System	05 Sep 2020 04:01:21

FDA-CBER-2022-1614-1779111

US3472001
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:42:27
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-05T00:00:59', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '8366d1a9-d067-4efe-aa3d-cdbbd93d72a5'	System	05 Sep 2020 04:01:21
User entered 'None (0)'	System	05 Sep 2020 04:01:21

FDA-CBER-2022-1614-1779112

US3472001
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:42:27
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-05T00:01:01', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '8366d1a9-d067-4efe-aa3d-cdbbd93d72a5'	(b) (4), (b) (6) System	05 Sep 2020 04:01:21
User entered 'None (0)'	System	05 Sep 2020 04:01:21

FDA-CBER-2022-1614-1779113

US3472001
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:42:27
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-05T00:01:03', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '8366d1a9-d067-4efe-aa3d-cdbbd93d72a5'	(b) (4), (b) (6) System	05 Sep 2020 04:01:21
User entered 'None (0)'	System	05 Sep 2020 04:01:21

FDA-CBER-2022-1614-1779114

US3472001
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:42:27
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-05T00:01:05', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '8366d1a9-d067-4efe-aa3d-cdbbd93d72a5'	(b) (4), (b) (6) System	05 Sep 2020 04:01:21
User entered 'None (0)'	System	05 Sep 2020 04:01:21

FDA-CBER-2022-1614-1779115

US3472001
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:42:27
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 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-05T00:01:08', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '8366d1a9-d067-4efe-aa3d-cdbbd93d72a5'	(b) (4), (b) (6) System	05 Sep 2020 04:01:21
User entered 'No (N)'	System	05 Sep 2020 04:01:21

FDA-CBER-2022-1614-1779116

US3472001
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:42:27
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-05T00:01:19', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '8366d1a9-d067-4efe-aa3d-cdbbd93d72a5'	(b) (4), (b) (6) System	05 Sep 2020 04:01:21
User entered '05 Sep 2020 00:01'	System	05 Sep 2020 04:01:21

FDA-CBER-2022-1614-1779117

US3472001
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:42:27
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
User entered '04 Sep 2020 12:00'	(b) (4), (b) (6) System	31 Aug 2020 15:27:47

FDA-CBER-2022-1614-1779118

US3472001
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:42:27
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
User entered '05 Sep 2020 11:59'	(b) (4), (b) (6) System	31 Aug 2020 15:27:47

FDA-CBER-2022-1614-1779119

US3472001
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:42:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
Data entry locked.	System	31 Aug 2020 15:27:47
User entered 'Day 6'	System	31 Aug 2020 15:27:47

FDA-CBER-2022-1614-1779120

US3472001
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:42:27
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-05T19:10:00', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'c73a9d09-b211-4ff0-8eb4-8ec920b416b7'	(b) (4), (b) (6) System	05 Sep 2020 23:10:25
User entered 'None (0)'	System	05 Sep 2020 23:10:25

FDA-CBER-2022-1614-1779121

US3472001
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:42:27
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-05T19:10:02', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'c73a9d09-b211-4ff0-8eb4-8ec920b416b7'	(b) (4), (b) (6) System	05 Sep 2020 23:10:25
User entered 'None (0)'	System	05 Sep 2020 23:10:25

FDA-CBER-2022-1614-1779122

US3472001
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:42:27
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-05T19:10:04', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'c73a9d09-b211-4ff0-8eb4-8ec920b416b7'	(b) (4), (b) (6) System	05 Sep 2020 23:10:25
User entered 'None (0)'	System	05 Sep 2020 23:10:25

FDA-CBER-2022-1614-1779123

US3472001
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:42:27
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-05T19:10:07', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'c73a9d09-b211-4ff0-8eb4-8ec920b416b7'	(b) (4), (b) (6) System	05 Sep 2020 23:10:25
User entered 'None (0)'	System	05 Sep 2020 23:10:25

FDA-CBER-2022-1614-1779124

US3472001
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:42:27
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-05T19:10:10', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'c73a9d09-b211-4ff0-8eb4-8ec920b416b7'	(b) (4), (b) (6) System	05 Sep 2020 23:10:25
User entered 'None (0)'	System	05 Sep 2020 23:10:25

FDA-CBER-2022-1614-1779125

US3472001
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:42:27
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-05T19:10:12', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'c73a9d09-b211-4ff0-8eb4-8ec920b416b7'	(b) (4), (b) (6) System	05 Sep 2020 23:10:25
User entered 'None (0)'	System	05 Sep 2020 23:10:25

FDA-CBER-2022-1614-1779126

US3472001
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:42:27
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 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-05T19:10:15', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'c73a9d09-b211-4ff0-8eb4-8ec920b416b7'	(b) (4), (b) (6) System	05 Sep 2020 23:10:25
User entered 'No (N)'	System	05 Sep 2020 23:10:25

FDA-CBER-2022-1614-1779127

US3472001
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:42:27
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-05T19:10:23', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'c73a9d09-b211-4ff0-8eb4-8ec920b416b7'	(b) (4), (b) (6) System	05 Sep 2020 23:10:25
User entered '05 Sep 2020 19:10'	System	05 Sep 2020 23:10:25

FDA-CBER-2022-1614-1779128

US3472001
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:42:27
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
User entered '05 Sep 2020 12:00'	(b) (4), (b) (6) System	31 Aug 2020 15:27:47

FDA-CBER-2022-1614-1779129

US3472001
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:42:27
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
User entered '06 Sep 2020 11:59'	(b) (4), (b) (6) System	31 Aug 2020 15:27:47

FDA-CBER-2022-1614-1779130

US3472001
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:42:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
Data entry locked.	System	31 Aug 2020 15:27:47
User entered 'Day 7'	System	31 Aug 2020 15:27:47

FDA-CBER-2022-1614-1779131

US3472001
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:42:27
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-06T17:44:52', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '846e2d20-d7ec-4839-bd3e-94285b396294'	(b) (4), (b) (6) System	06 Sep 2020 21:45:17
User entered 'None (0)'	System	06 Sep 2020 21:45:17

FDA-CBER-2022-1614-1779132

US3472001
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:42:27
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-06T17:44:53', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '846e2d20-d7ec-4839-bd3e-94285b396294'	(b) (4), (b) (6) System	06 Sep 2020 21:45:17
User entered 'None (0)'	System	06 Sep 2020 21:45:17

FDA-CBER-2022-1614-1779133

US3472001
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:42:27
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-06T17:44:55', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '846e2d20-d7ec-4839-bd3e-94285b396294'	(b) (4), (b) (6) System	06 Sep 2020 21:45:17
User entered 'None (0)'	System	06 Sep 2020 21:45:17

FDA-CBER-2022-1614-1779134

US3472001
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:42:27
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-06T17:44:56', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '846e2d20-d7ec-4839-bd3e-94285b396294'	(b) (4), (b) (6) System	06 Sep 2020 21:45:17
User entered 'None (0)'	System	06 Sep 2020 21:45:17

US3472001
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:42:27
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-06T17:44:58', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '846e2d20-d7ec-4839-bd3e-94285b396294'	(b) (4), (b) (6) System	06 Sep 2020 21:45:17
User entered 'None (0)'	System	06 Sep 2020 21:45:17

FDA-CBER-2022-1614-1779136

US3472001
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:42:27
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-06T17:45:01', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '846e2d20-d7ec-4839-bd3e-94285b396294'	(b) (4), (b) (6) System	06 Sep 2020 21:45:17
User entered 'None (0)'	System	06 Sep 2020 21:45:17

FDA-CBER-2022-1614-1779137

US3472001
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:42:27
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 01:17:24
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-06T17:45:06', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '846e2d20-d7ec-4839-bd3e-94285b396294'	System	06 Sep 2020 21:45:17
User entered 'No (N)'	System	06 Sep 2020 21:45:17

FDA-CBER-2022-1614-1779138

US3472001
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:42:27
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-09-06T17:45:15', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '846e2d20-d7ec-4839-bd3e-94285b396294'	(b) (4), (b) (6) System	06 Sep 2020 21:45:17
User entered '06 Sep 2020 17:45'	System	06 Sep 2020 21:45:17

FDA-CBER-2022-1614-1779139

US3472001
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:42:27
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
User entered '06 Sep 2020 12:00'	(b) (4), (b) (6) System	31 Aug 2020 15:27:47

FDA-CBER-2022-1614-1779140

US3472001
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:42:27
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
User entered '07 Sep 2020 11:59'	(b) (4), (b) (6) System	31 Aug 2020 15:27:47

FDA-CBER-2022-1614-1779141

US3472001
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:42:27
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
User entered 'Yes (Y)'	Jie Ho (b) (4)	07 Sep 2020 13:46:51

FDA-CBER-2022-1614-1779142

US3472001
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:42:27
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
User entered '7 Sep 2020'	Jie Ho (b) (4)	07 Sep 2020 13:46:51

FDA-CBER-2022-1614-1779143

US3472001
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:42:27
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
User entered 'Contact Made (CONTACT MADE)'	Jie Ho (b) (4)	07 Sep 2020 13:46:51

US3472001
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:42:27
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
User entered empty.	Jie Ho (b) (4)	07 Sep 2020 13:46:51

FDA-CBER-2022-1614-1779145

US3472001
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:42:27
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
User entered 'Yes (Y)'	Jie Ho (b) (4)	07 Sep 2020 13:46:58

FDA-CBER-2022-1614-1779146

US3472001
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:42:27
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered '1'	System	07 Sep 2020 13:46:58

FDA-CBER-2022-1614-1779147

US3472001
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:42:27
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 18:41:32

FDA-CBER-2022-1614-1779148

US3472001
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:42:27
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
User entered '14 Sep 2020'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 18:41:32

FDA-CBER-2022-1614-1779149

US3472001
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:42:27
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 18:41:32

FDA-CBER-2022-1614-1779150

US3472001
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:42:27
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 18:41:32

FDA-CBER-2022-1614-1779151

US3472001
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:42:27
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Sep 2020 18:41:37

FDA-CBER-2022-1614-1779152

US3472001
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:42:27
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered '1'	System	14 Sep 2020 18:41:37

FDA-CBER-2022-1614-1779153

US3472001
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:42:27
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 18:38:07

FDA-CBER-2022-1614-1779154

US3472001
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:42:27
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
User entered '21 Sep 2020'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 18:38:07

FDA-CBER-2022-1614-1779155

US3472001
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:42:27
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 18:38:07

FDA-CBER-2022-1614-1779156

US3472001
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:42:27
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 18:38:07

FDA-CBER-2022-1614-1779157

US3472001
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:42:27
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 18:38:14

FDA-CBER-2022-1614-1779158

US3472001
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:42:27
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered '1'	System	21 Sep 2020 18:38:14

FDA-CBER-2022-1614-1779159

US3472001
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:42:27
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:19:20

FDA-CBER-2022-1614-1779160

US3472001
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:42:27
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
User entered '01 Oct 2020'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:19:20

FDA-CBER-2022-1614-1779161

US3472001
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:42:27
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 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:19:20

FDA-CBER-2022-1614-1779162

US3472001
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:42:27
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered 'VISIT2'	System	01 Oct 2020 17:19:20

FDA-CBER-2022-1614-1779163

US3472001
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:42:27
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	01 Oct 2020 17:25:36

FDA-CBER-2022-1614-1779164

US3472001
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:42:27
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:25:36

FDA-CBER-2022-1614-1779165

US3472001
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:42:27
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
User entered '01 Oct 2020'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:25:36

FDA-CBER-2022-1614-1779166

US3472001
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:42:27
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
User entered '12:52'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:25:36

FDA-CBER-2022-1614-1779167

US3472001
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:42:27
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered '01 Oct 2020 12:52'	System	01 Oct 2020 17:25:36

FDA-CBER-2022-1614-1779168

US3472001
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:42:27
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
User entered '36.7' C	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:25:36

FDA-CBER-2022-1614-1779169

US3472001
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:42:27
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:25:36

FDA-CBER-2022-1614-1779170

US3472001
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:42:27
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:25:36

FDA-CBER-2022-1614-1779171

US3472001
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:42:27
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
User entered '78'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:25:36

FDA-CBER-2022-1614-1779172

US3472001
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:42:27
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered 'bpm'	System	01 Oct 2020 17:25:36

FDA-CBER-2022-1614-1779173

US3472001
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:42:27
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
User entered '18'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:25:36

FDA-CBER-2022-1614-1779174

US3472001
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:42:27
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered 'breaths/min'	System	01 Oct 2020 17:25:36

FDA-CBER-2022-1614-1779175

US3472001
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:42:27
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
User entered '117'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:25:36

FDA-CBER-2022-1614-1779176

US3472001
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:42:27
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered 'mmHg'	System	01 Oct 2020 17:25:36

FDA-CBER-2022-1614-1779177

US3472001
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:42:27
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
User entered '80'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:25:36

FDA-CBER-2022-1614-1779178

US3472001
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 17:42:27
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered 'mmHg'	System	01 Oct 2020 17:25:36

FDA-CBER-2022-1614-1779179

US3472001
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:42:27
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	01 Oct 2020 17:25:36

FDA-CBER-2022-1614-1779180

US3472001
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:42:27
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Oct 2020 18:12:04
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Oct 2020 18:12:04
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	01 Oct 2020 18:12:04
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Oct 2020 17:25:36
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 17:25:36

FDA-CBER-2022-1614-1779181

US3472001
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:42:27
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
User entered '01 Oct 2020' reason for change: New Information	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:12:04
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 17:25:36

US3472001
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:42:27
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
User entered '14:10' reason for change: New Information	(b) (4), (b) (6)	01 Oct 2020 18:12:04
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 17:25:36

FDA-CBER-2022-1614-1779183

US3472001
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:42:27
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered '01 Oct 2020 14:10'	System	01 Oct 2020 18:12:04
User entered empty.	System	01 Oct 2020 17:25:36

FDA-CBER-2022-1614-1779184

US3472001
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:42:27
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
User entered '36.9' C reason for change: New Information	(b) (4), (b) (6)	01 Oct 2020 18:12:04
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 17:25:36

FDA-CBER-2022-1614-1779185

US3472001
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:42:27
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
User entered 'Oral (Oral)' reason for change: New Information	(b) (4), (b) (6)	01 Oct 2020 18:12:04
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 17:25:36

FDA-CBER-2022-1614-1779186

US3472001
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:42:27
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:25:36

FDA-CBER-2022-1614-1779187

US3472001
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:42:27
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
User entered '64' reason for change: New Information	(b) (4), (b) (6)	01 Oct 2020 18:12:04
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 17:25:36

FDA-CBER-2022-1614-1779188

US3472001
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:42:27
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered 'bpm'	System	01 Oct 2020 18:12:04
User entered empty.	System	01 Oct 2020 17:25:36

FDA-CBER-2022-1614-1779189

US3472001
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:42:27
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
User entered '18' reason for change: New Information	(b) (4), (b) (6)	01 Oct 2020 18:12:04
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 17:25:36

FDA-CBER-2022-1614-1779190

US3472001
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:42:27
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered 'breaths/min'	System	01 Oct 2020 18:12:04
User entered empty.	System	01 Oct 2020 17:25:36

FDA-CBER-2022-1614-1779191

US3472001
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:42:27
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
User entered '136' reason for change: New Information	(b) (4), (b) (6)	01 Oct 2020 18:12:04
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 17:25:36

FDA-CBER-2022-1614-1779192

US3472001
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:42:27
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered 'mmHg'	System	01 Oct 2020 18:12:04
User entered empty.	System	01 Oct 2020 17:25:36

FDA-CBER-2022-1614-1779193

US3472001
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:42:27
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
User entered '87' reason for change: New Information	(b) (4), (b) (6)	01 Oct 2020 18:12:04
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 17:25:36

FDA-CBER-2022-1614-1779194

US3472001
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 17:42:27
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered 'mmHg'	System	01 Oct 2020 18:12:04
User entered empty.	System	01 Oct 2020 17:25:36

FDA-CBER-2022-1614-1779195

US3472001
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 17:42:27
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
User entered 'Yes (Y)' reason for change: Data Entry Error	Jie Ho (b) (4)	01 Oct 2020 19:50:36
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 17:25:42

FDA-CBER-2022-1614-1779196

US3472001
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 17:42:27
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
User entered '01 Oct 2020' reason for change: Data Entry Error	Jie Ho (b) (4)	01 Oct 2020 19:50:36
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 17:25:42

FDA-CBER-2022-1614-1779197

US3472001
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 17:42:27
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:40:49

FDA-CBER-2022-1614-1779198

US3472001
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 17:42:27
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:40:49

FDA-CBER-2022-1614-1779199

US3472001

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:42:27

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)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 17:40:49

US3472001
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 17:42:27
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered 'MRNA-1273 OR PLACEBO'	System	01 Oct 2020 17:40:49

FDA-CBER-2022-1614-1779201

US3472001
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 17:42:27
What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
User entered '01 Oct 2020'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:40:49

FDA-CBER-2022-1614-1779202

US3472001
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 17:42:27
What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
User entered '13:38'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:40:49

FDA-CBER-2022-1614-1779203

US3472001
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 17:42:27
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered '01 Oct 2020 13:38'	System	01 Oct 2020 17:40:49

FDA-CBER-2022-1614-1779204

US3472001
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 17:42:27
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
User closed query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	System	01 Oct 2020 17:40:59
Query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' answered by data change (Site from System).	System	01 Oct 2020 17:40:59
User entered 'Right Arm (RIGHT ARM)' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Oct 2020 17:40:59
User opened query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	System	01 Oct 2020 17:40:49
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	01 Oct 2020 17:40:49

FDA-CBER-2022-1614-1779205

US3472001
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 17:42:27
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered 'ONCE'	System	01 Oct 2020 17:40:49

FDA-CBER-2022-1614-1779206

US3472001
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 17:42:27
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered 'INTRAMUSCULAR'	System	01 Oct 2020 17:40:49

FDA-CBER-2022-1614-1779207

US3472001
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 17:42:27
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:41:21

FDA-CBER-2022-1614-1779208

US3472001
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 17:42:27
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
User entered '01 Oct 2020'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:41:21

FDA-CBER-2022-1614-1779209

US3472001
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 17:42:27
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
User entered '13:20'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:41:21

FDA-CBER-2022-1614-1779210

US3472001
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 17:42:27
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered '01 Oct 2020 13:20'	System	01 Oct 2020 17:41:21

FDA-CBER-2022-1614-1779211

US3472001
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab
Generated On: 09 Jun 2021 17:42:27
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
User entered '01 Oct 2020'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:41:39

FDA-CBER-2022-1614-1779212

US3472001
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 17:42:27
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	01 Oct 2020 17:41:39

FDA-CBER-2022-1614-1779213

US3472001
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 17:42:27
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:41:39

FDA-CBER-2022-1614-1779214

US3472001
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 17:42:27
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
User entered '13:00'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:41:39

FDA-CBER-2022-1614-1779215

US3472001
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 17:42:27
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered '01 Oct 2020 13:00'	System	01 Oct 2020 17:41:39

FDA-CBER-2022-1614-1779216

US3472001
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 17:42:27
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	01 Oct 2020 17:41:39

FDA-CBER-2022-1614-1779217

US3472001
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 17:42:27
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:41:39

FDA-CBER-2022-1614-1779218

US3472001
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 17:42:27
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:41:39

FDA-CBER-2022-1614-1779219

US3472001
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 17:42:27
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered empty.	System	01 Oct 2020 17:41:39

FDA-CBER-2022-1614-1779220

US3472001
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:42:27
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:41:45

FDA-CBER-2022-1614-1779221

US3472001
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:42:27
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered '1'	System	01 Oct 2020 17:41:45

FDA-CBER-2022-1614-1779222

US3472001
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 17:42:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
Data entry locked.	System	01 Oct 2020 17:40:49
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Oct 2020 17:40:49

FDA-CBER-2022-1614-1779223

US3472001
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 17:42:27
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-01T14:10:34', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '7af04e22-87eb-4883-8f10-24579f9ca0fc'	(b) (4), (b) (6) System	01 Oct 2020 18:10:58
User entered 'Yes (Y)'	System	01 Oct 2020 18:10:58

FDA-CBER-2022-1614-1779224

US3472001
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 17:42:27
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-01T14:10:44', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '7af04e22-87eb-4883-8f10-24579f9ca0fc'	(b) (4), (b) (6) System	01 Oct 2020 18:10:58
User entered '98.4'	System	01 Oct 2020 18:10:58

FDA-CBER-2022-1614-1779225

US3472001
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 17:42:27
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-01T14:10:48', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '7af04e22-87eb-4883-8f10-24579f9ca0fc'	(b) (4), (b) (6) System	01 Oct 2020 18:10:58
User entered 'No (N)'	System	01 Oct 2020 18:10:58

FDA-CBER-2022-1614-1779226

US3472001
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 17:42:27
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-01T14:10:56', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '7af04e22-87eb-4883-8f10-24579f9ca0fc'	(b) (4), (b) (6) System	01 Oct 2020 18:10:58
User entered '01 Oct 2020 14:10'	System	01 Oct 2020 18:10:58

FDA-CBER-2022-1614-1779227

US3472001
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 17:42:27
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
User entered '01 Oct 2020 13:58'	(b) (4), (b) (6) System	01 Oct 2020 17:40:49

FDA-CBER-2022-1614-1779228

US3472001
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 17:42:27
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
User entered '01 Oct 2020 16:28'	(b) (4), (b) (6) System	01 Oct 2020 17:40:49

FDA-CBER-2022-1614-1779229

US3472001
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 17:42:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
Data entry locked.	System	01 Oct 2020 17:40:49
User entered 'Day 1, after vaccination (at home)'	System	01 Oct 2020 17:40:49

FDA-CBER-2022-1614-1779230

US3472001
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 17:42:27
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-01T22:33:58', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '35720366-f9ea-46a7-af27-584dadcf2b7a'	(b) (4), (b) (6) System	02 Oct 2020 02:34:20
User entered 'Yes (Y)'	System	02 Oct 2020 02:34:20

FDA-CBER-2022-1614-1779231

US3472001
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 17:42:27
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-01T22:34:04', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '35720366-f9ea-46a7-af27-584dadcf2b7a'	(b) (4), (b) (6) System	02 Oct 2020 02:34:20
User entered '97.7'	System	02 Oct 2020 02:34:20

FDA-CBER-2022-1614-1779232

US3472001
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 17:42:27
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-01T22:34:08', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '35720366-f9ea-46a7-af27-584dadcf2b7a'	(b) (4), (b) (6) System	02 Oct 2020 02:34:20
User entered 'No (N)'	System	02 Oct 2020 02:34:20

FDA-CBER-2022-1614-1779233

US3472001
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 17:42:27
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-01T22:34:17', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '35720366-f9ea-46a7-af27-584dadcf2b7a'	System	02 Oct 2020 02:34:20
User entered '01 Oct 2020 22:34'	System	02 Oct 2020 02:34:20

FDA-CBER-2022-1614-1779234

US3472001
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 17:42:27
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
User entered '01 Oct 2020 17:23'	(b) (4), (b) (6) System	01 Oct 2020 17:40:49

FDA-CBER-2022-1614-1779235

US3472001
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 17:42:27
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
User entered '02 Oct 2020 11:59'	(b) (4), (b) (6) System	01 Oct 2020 17:40:49

FDA-CBER-2022-1614-1779236

US3472001
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 17:42:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
Data entry locked.	System	01 Oct 2020 17:40:49
User entered 'Day 2'	System	01 Oct 2020 17:40:49

FDA-CBER-2022-1614-1779237

US3472001
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 17:42:27
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-02T18:14:49', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '20007b77-de20-414e-96ce-4c2dc507bf79'	System	02 Oct 2020 22:15:12
User entered 'Yes (Y)'	System	02 Oct 2020 22:15:12

FDA-CBER-2022-1614-1779238

US3472001
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 17:42:27
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-02T18:14:57', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '20007b77-de20-414e-96ce-4c2dc507bf79'	System	02 Oct 2020 22:15:12
User entered '98.3'	System	02 Oct 2020 22:15:12

FDA-CBER-2022-1614-1779239

US3472001
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 17:42:27
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-02T18:15:01', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '20007b77-de20-414e-96ce-4c2dc507bf79'	(b) (4), (b) (6) System	02 Oct 2020 22:15:12
User entered 'No (N)'	System	02 Oct 2020 22:15:12

FDA-CBER-2022-1614-1779240

US3472001
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 17:42:27
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-02T18:15:08', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '20007b77-de20-414e-96ce-4c2dc507bf79'	System	02 Oct 2020 22:15:12
User entered '02 Oct 2020 18:15'	System	02 Oct 2020 22:15:12

FDA-CBER-2022-1614-1779241

US3472001
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 17:42:27
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
User entered '02 Oct 2020 12:00'	(b) (4), (b) (6) System	01 Oct 2020 17:40:49

FDA-CBER-2022-1614-1779242

US3472001
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 17:42:27
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
User entered '03 Oct 2020 11:59'	(b) (4), (b) (6) System	01 Oct 2020 17:40:49

FDA-CBER-2022-1614-1779243

US3472001
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:42:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
Data entry locked.	System	01 Oct 2020 17:40:49
User entered 'Day 3'	System	01 Oct 2020 17:40:49

FDA-CBER-2022-1614-1779244

US3472001
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:42:27
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-03T19:10:41', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '0a3fe86b-0fab-466f-95d4-7cccd89093d2'	(b) (4), (b) (6) System	03 Oct 2020 23:11:04
User entered 'Yes (Y)'	System	03 Oct 2020 23:11:04

FDA-CBER-2022-1614-1779245

US3472001
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:42:27
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-03T19:10:55', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '0a3fe86b-0fab-466f-95d4-7cccd89093d2'	System	03 Oct 2020 23:11:04
User entered '98.4'	System	03 Oct 2020 23:11:04

FDA-CBER-2022-1614-1779246

US3472001
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:42:27
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-03T19:10:58', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '0a3fe86b-0fab-466f-95d4-7cccd89093d2'	(b) (4), (b) (6) System	03 Oct 2020 23:11:04
User entered 'No (N)'	System	03 Oct 2020 23:11:04

FDA-CBER-2022-1614-1779247

US3472001
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:42:27
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-03T19:11:02', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '0a3fe86b-0fab-466f-95d4-7cccd89093d2'	System	03 Oct 2020 23:11:04
User entered '03 Oct 2020 19:11'	System	03 Oct 2020 23:11:04

FDA-CBER-2022-1614-1779248

US3472001
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:42:27
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
User entered '03 Oct 2020 12:00'	(b) (4), (b) (6) System	01 Oct 2020 17:40:49

FDA-CBER-2022-1614-1779249

US3472001
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 17:42:27
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
User entered '04 Oct 2020 11:59'	(b) (4), (b) (6) System	01 Oct 2020 17:40:49

FDA-CBER-2022-1614-1779250

US3472001
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:42:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
Data entry locked.	System	01 Oct 2020 17:40:49
User entered 'Day 4'	System	01 Oct 2020 17:40:49

FDA-CBER-2022-1614-1779251

US3472001
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:42:27
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-04T19:47:02', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '01431a11-4a33-461b-9291-0e034bd6dd87'	(b) (4), (b) (6) System	04 Oct 2020 23:47:21
User entered 'Yes (Y)'	System	04 Oct 2020 23:47:21

FDA-CBER-2022-1614-1779252

US3472001
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:42:27
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-04T19:47:08', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '01431a11-4a33-461b-9291-0e034bd6dd87'	System	04 Oct 2020 23:47:21
User entered '98.1'	System	04 Oct 2020 23:47:21

FDA-CBER-2022-1614-1779253

US3472001
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:42:27
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-04T19:47:12', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '01431a11-4a33-461b-9291-0e034bd6dd87'	(b) (4), (b) (6) System	04 Oct 2020 23:47:21
User entered 'No (N)'	System	04 Oct 2020 23:47:21

FDA-CBER-2022-1614-1779254

US3472001
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:42:27
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-04T19:47:18', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '01431a11-4a33-461b-9291-0e034bd6dd87'	System	04 Oct 2020 23:47:21
User entered '04 Oct 2020 19:47'	System	04 Oct 2020 23:47:21

FDA-CBER-2022-1614-1779255

US3472001
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:42:27
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
User entered '04 Oct 2020 12:00'	(b) (4), (b) (6) System	01 Oct 2020 17:40:49

FDA-CBER-2022-1614-1779256

US3472001
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 17:42:27
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
User entered '05 Oct 2020 11:59'	(b) (4), (b) (6) System	01 Oct 2020 17:40:49

FDA-CBER-2022-1614-1779257

US3472001
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 17:42:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
Data entry locked.	System	01 Oct 2020 17:40:49
User entered 'Day 5'	System	01 Oct 2020 17:40:49

FDA-CBER-2022-1614-1779258

US3472001
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 17:42:27
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-05T19:32:01', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'f3601de6-9135-4b30-a574-36f2fb5b5965'	(b) (4), (b) (6) System	05 Oct 2020 23:32:24
User entered 'Yes (Y)'	System	05 Oct 2020 23:32:24

FDA-CBER-2022-1614-1779259

US3472001
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 17:42:27
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-05T19:32:08', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'f3601de6-9135-4b30-a574-36f2fb5b5965'	(b) (4), (b) (6) System	05 Oct 2020 23:32:24
User entered '97.6'	System	05 Oct 2020 23:32:24

FDA-CBER-2022-1614-1779260

US3472001
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 17:42:27
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-05T19:32:11', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'f3601de6-9135-4b30-a574-36f2fb5b5965'	(b) (4), (b) (6) System	05 Oct 2020 23:32:24
User entered 'No (N)'	System	05 Oct 2020 23:32:24

FDA-CBER-2022-1614-1779261

US3472001
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 17:42:27
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-05T19:32:17', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'f3601de6-9135-4b30-a574-36f2fb5b5965'	(b) (4), (b) (6) System	05 Oct 2020 23:32:24
User entered '05 Oct 2020 19:32'	System	05 Oct 2020 23:32:24

US3472001
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 17:42:27
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
User entered '05 Oct 2020 12:00'	(b) (4), (b) (6) System	01 Oct 2020 17:40:49

FDA-CBER-2022-1614-1779263

US3472001
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 17:42:27
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
User entered '06 Oct 2020 11:59'	(b) (4), (b) (6) System	01 Oct 2020 17:40:49

FDA-CBER-2022-1614-1779264

US3472001
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:42:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
Data entry locked.	System	01 Oct 2020 17:40:49
User entered 'Day 6'	System	01 Oct 2020 17:40:49

FDA-CBER-2022-1614-1779265

US3472001
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:42:27
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-06T20:32:05', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '8e666d8f-711f-4be8-a32d-ec00e40930b6'	(b) (4), (b) (6) System	07 Oct 2020 00:32:23
User entered 'Yes (Y)'	System	07 Oct 2020 00:32:23

FDA-CBER-2022-1614-1779266

US3472001
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:42:27
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-06T20:32:10', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '8e666d8f-711f-4be8-a32d-ec00e40930b6'	(b) (4), (b) (6) System	07 Oct 2020 00:32:23
User entered '98.3'	System	07 Oct 2020 00:32:23

FDA-CBER-2022-1614-1779267

US3472001
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:42:27
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-06T20:32:15', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '8e666d8f-711f-4be8-a32d-ec00e40930b6'	(b) (4), (b) (6) System	07 Oct 2020 00:32:23
User entered 'No (N)'	System	07 Oct 2020 00:32:23

FDA-CBER-2022-1614-1779268

US3472001
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:42:27
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-06T20:32:20', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '8e666d8f-711f-4be8-a32d-ec00e40930b6'	(b) (4), (b) (6) System	07 Oct 2020 00:32:23
User entered '06 Oct 2020 20:32'	System	07 Oct 2020 00:32:23

FDA-CBER-2022-1614-1779269

US3472001
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:42:27
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
User entered '06 Oct 2020 12:00'	(b) (4), (b) (6) System	01 Oct 2020 17:40:49

FDA-CBER-2022-1614-1779270

US3472001
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 17:42:27
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
User entered '07 Oct 2020 11:59'	(b) (4), (b) (6) System	01 Oct 2020 17:40:49

FDA-CBER-2022-1614-1779271

US3472001
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 17:42:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
Data entry locked.	System	01 Oct 2020 17:40:49
User entered 'Day 7'	System	01 Oct 2020 17:40:49

FDA-CBER-2022-1614-1779272

US3472001
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 17:42:27
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-07T20:26:46', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '3a54e848-af47-4842-afe5-669ce8634844'	(b) (4), (b) (6) System	08 Oct 2020 00:27:07
User entered 'Yes (Y)'	System	08 Oct 2020 00:27:07

FDA-CBER-2022-1614-1779273

US3472001
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 17:42:27
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-07T20:26:53', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '3a54e848-af47-4842-afe5-669ce8634844'	System	08 Oct 2020 00:27:07
User entered '98.4'	System	08 Oct 2020 00:27:07

FDA-CBER-2022-1614-1779274

US3472001
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 17:42:27
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-07T20:26:57', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '3a54e848-af47-4842-afe5-669ce8634844'	(b) (4), (b) (6) System	08 Oct 2020 00:27:07
User entered 'No (N)'	System	08 Oct 2020 00:27:07

FDA-CBER-2022-1614-1779275

US3472001
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 17:42:27
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-07T20:27:01', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '3a54e848-af47-4842-afe5-669ce8634844'	System	08 Oct 2020 00:27:07
User entered '07 Oct 2020 20:27'	System	08 Oct 2020 00:27:07

FDA-CBER-2022-1614-1779276

US3472001
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 17:42:27
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
User entered '07 Oct 2020 12:00'	(b) (4), (b) (6) System	01 Oct 2020 17:40:49

FDA-CBER-2022-1614-1779277

US3472001
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 17:42:27
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
User entered '08 Oct 2020 11:59'	(b) (4), (b) (6) System	01 Oct 2020 17:40:49

FDA-CBER-2022-1614-1779278

US3472001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:42:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
Data entry locked.	System	01 Oct 2020 17:40:49
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Oct 2020 17:40:49

FDA-CBER-2022-1614-1779279

US3472001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:42:27
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 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-01T14:11:12', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '9d29eaf1-75df-490a-a20e-cdac5de20473'	(b) (4), (b) (6) System	01 Oct 2020 18:11:27
User entered 'None (1)'	System	01 Oct 2020 18:11:27

FDA-CBER-2022-1614-1779280

US3472001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:42:27
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-01T14:11:16', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '9d29eaf1-75df-490a-a20e-cdac5de20473'	(b) (4), (b) (6) System	01 Oct 2020 18:11:27
User entered 'No (N)'	System	01 Oct 2020 18:11:27

FDA-CBER-2022-1614-1779281

US3472001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:42:27
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-01T14:11:19', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '9d29eaf1-75df-490a-a20e-cdac5de20473'	(b) (4), (b) (6) System	01 Oct 2020 18:11:27
User entered 'No (N)'	System	01 Oct 2020 18:11:27

FDA-CBER-2022-1614-1779282

US3472001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:42:27

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 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-01T14:11:22', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '9d29eaf1-75df-490a-a20e-cdac5de20473'	(b) (4), (b) (6) System	01 Oct 2020 18:11:27
User entered 'None (1)'	System	01 Oct 2020 18:11:27

US3472001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:42:27
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-01T14:11:25', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '9d29eaf1-75df-490a-a20e-cdac5de20473'	(b) (4), (b) (6) System	01 Oct 2020 18:11:27
User entered '01 Oct 2020 14:11'	System	01 Oct 2020 18:11:27

FDA-CBER-2022-1614-1779284

US3472001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:42:27
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
User entered '01 Oct 2020 13:58'	(b) (4), (b) (6) System	01 Oct 2020 17:40:49

FDA-CBER-2022-1614-1779285

US3472001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 17:42:27
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
User entered '01 Oct 2020 16:28'	(b) (4), (b) (6) System	01 Oct 2020 17:40:49

FDA-CBER-2022-1614-1779286

US3472001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:42:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
Data entry locked.	System	01 Oct 2020 17:40:49
User entered 'Day 1, after vaccination (at home)'	System	01 Oct 2020 17:40:49

FDA-CBER-2022-1614-1779287

US3472001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:42:27
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 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-01T22:34:25', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '661865d6-c808-429c-9448-6b9d04ac6cf7'	(b) (4), (b) (6) System	02 Oct 2020 02:34:44
User entered 'None (1)'	System	02 Oct 2020 02:34:44

FDA-CBER-2022-1614-1779288

US3472001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:42:27
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-01T22:34:29', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '661865d6-c808-429c-9448-6b9d04ac6cf7'	(b) (4), (b) (6) System	02 Oct 2020 02:34:44
User entered 'No (N)'	System	02 Oct 2020 02:34:44

FDA-CBER-2022-1614-1779289

US3472001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:42:27
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-01T22:34:31', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '661865d6-c808-429c-9448-6b9d04ac6cf7'	(b) (4), (b) (6) System	02 Oct 2020 02:34:44
User entered 'No (N)'	System	02 Oct 2020 02:34:44

FDA-CBER-2022-1614-1779290

US3472001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:42:27
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 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-01T22:34:36', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '661865d6-c808-429c-9448-6b9d04ac6cf7'	(b) (4), (b) (6) System	02 Oct 2020 02:34:44
User entered 'None (1)'	System	02 Oct 2020 02:34:44

FDA-CBER-2022-1614-1779291

US3472001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:42:27
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-01T22:34:40', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '661865d6-c808-429c-9448-6b9d04ac6cf7'	System	02 Oct 2020 02:34:44
User entered '01 Oct 2020 22:34'	System	02 Oct 2020 02:34:44

FDA-CBER-2022-1614-1779292

US3472001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:42:27
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
User entered '01 Oct 2020 17:23'	(b) (4), (b) (6) System	01 Oct 2020 17:40:49

FDA-CBER-2022-1614-1779293

US3472001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 17:42:27
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
User entered '02 Oct 2020 11:59'	(b) (4), (b) (6) System	01 Oct 2020 17:40:49

FDA-CBER-2022-1614-1779294

US3472001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:42:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
Data entry locked.	System	01 Oct 2020 17:40:49
User entered 'Day 2'	System	01 Oct 2020 17:40:49

FDA-CBER-2022-1614-1779295

US3472001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:42:27
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 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-02T18:15:30', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '910ba170-37de-44e9-abcb-16f2da3b796e'	(b) (4), (b) (6) System	02 Oct 2020 22:15:49
User entered 'None (1)'	System	02 Oct 2020 22:15:49

FDA-CBER-2022-1614-1779296

US3472001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:42:27
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-02T18:15:34', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '910ba170-37de-44e9-abcb-16f2da3b796e'	System	02 Oct 2020 22:15:49
User entered 'No (N)'	System	02 Oct 2020 22:15:49

FDA-CBER-2022-1614-1779297

US3472001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:42:27
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-02T18:15:36', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '910ba170-37de-44e9-abcb-16f2da3b796e'	System	02 Oct 2020 22:15:49
User entered 'No (N)'	System	02 Oct 2020 22:15:49

FDA-CBER-2022-1614-1779298

US3472001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:42:27
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 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-02T18:15:41', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '910ba170-37de-44e9-abcb-16f2da3b796e'	(b) (4), (b) (6) System	02 Oct 2020 22:15:49
User entered 'None (1)'	System	02 Oct 2020 22:15:49

FDA-CBER-2022-1614-1779299

US3472001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:42:27
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-02T18:15:46', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '910ba170-37de-44e9-abcb-16f2da3b796e'	System	02 Oct 2020 22:15:49
User entered '02 Oct 2020 18:15'	System	02 Oct 2020 22:15:49

FDA-CBER-2022-1614-1779300

US3472001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:42:27
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
User entered '02 Oct 2020 12:00'	(b) (4), (b) (6) System	01 Oct 2020 17:40:49

FDA-CBER-2022-1614-1779301

US3472001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 17:42:27
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
User entered '03 Oct 2020 11:59'	(b) (4), (b) (6) System	01 Oct 2020 17:40:49

FDA-CBER-2022-1614-1779302

US3472001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:42:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
Data entry locked.	System	01 Oct 2020 17:40:49
User entered 'Day 3'	System	01 Oct 2020 17:40:49

FDA-CBER-2022-1614-1779303

US3472001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:42:27
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 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-03T19:11:23', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '46064d2e-6c59-43af-91fc-416ab4b26157'	(b) (4), (b) (6) System	03 Oct 2020 23:11:40
User entered 'None (1)'	System	03 Oct 2020 23:11:40

FDA-CBER-2022-1614-1779304

US3472001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:42:27
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-03T19:11:26', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '46064d2e-6c59-43af-91fc-416ab4b26157'	(b) (4), (b) (6) System	03 Oct 2020 23:11:40
User entered 'No (N)'	System	03 Oct 2020 23:11:40

FDA-CBER-2022-1614-1779305

US3472001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:42:27
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-03T19:11:29', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '46064d2e-6c59-43af-91fc-416ab4b26157'	(b) (4), (b) (6) System	03 Oct 2020 23:11:40
User entered 'No (N)'	System	03 Oct 2020 23:11:40

FDA-CBER-2022-1614-1779306

US3472001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:42:27

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 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-03T19:11:32', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '46064d2e-6c59-43af-91fc-416ab4b26157'	(b) (4), (b) (6) System	03 Oct 2020 23:11:40
User entered 'None (1)'	System	03 Oct 2020 23:11:40

US3472001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:42:27
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-03T19:11:36', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '46064d2e-6c59-43af-91fc-416ab4b26157'	System	03 Oct 2020 23:11:40
User entered '03 Oct 2020 19:11'	System	03 Oct 2020 23:11:40

FDA-CBER-2022-1614-1779308

US3472001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:42:27
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
User entered '03 Oct 2020 12:00'	(b) (4), (b) (6) System	01 Oct 2020 17:40:49

FDA-CBER-2022-1614-1779309

US3472001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 17:42:27
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
User entered '04 Oct 2020 11:59'	(b) (4), (b) (6) System	01 Oct 2020 17:40:49

FDA-CBER-2022-1614-1779310

US3472001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:42:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
Data entry locked.	System	01 Oct 2020 17:40:49
User entered 'Day 4'	System	01 Oct 2020 17:40:49

FDA-CBER-2022-1614-1779311

US3472001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:42:27
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 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-04T19:47:23', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '7f16b5c5-82a3-410d-9056-bdc97b8eb88e'	(b) (4), (b) (6) System	04 Oct 2020 23:47:44
User entered 'None (1)'	System	04 Oct 2020 23:47:44

FDA-CBER-2022-1614-1779312

US3472001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:42:27
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-04T19:47:26', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '7f16b5c5-82a3-410d-9056-bdc97b8eb88e'	System	04 Oct 2020 23:47:44
User entered 'No (N)'	System	04 Oct 2020 23:47:44

FDA-CBER-2022-1614-1779313

US3472001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:42:27
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-04T19:47:30', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '7f16b5c5-82a3-410d-9056-bdc97b8eb88e'	System	04 Oct 2020 23:47:44
User entered 'No (N)'	System	04 Oct 2020 23:47:44

FDA-CBER-2022-1614-1779314

US3472001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:42:27

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 01:17:24
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-04T19:47:34', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '7f16b5c5-82a3-410d-9056-bdc97b8eb88e'	System	04 Oct 2020 23:47:44
User entered 'None (1)'	System	04 Oct 2020 23:47:44

US3472001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:42:27
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-04T19:47:42', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '7f16b5c5-82a3-410d-9056-bdc97b8eb88e'	(b) (4), (b) (6) System	04 Oct 2020 23:47:44
User entered '04 Oct 2020 19:47'	System	04 Oct 2020 23:47:44

FDA-CBER-2022-1614-1779316

US3472001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:42:27
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
User entered '04 Oct 2020 12:00'	(b) (4), (b) (6) System	01 Oct 2020 17:40:49

FDA-CBER-2022-1614-1779317

US3472001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 17:42:27
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
User entered '05 Oct 2020 11:59'	(b) (4), (b) (6) System	01 Oct 2020 17:40:49

FDA-CBER-2022-1614-1779318

US3472001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:42:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
Data entry locked.	System	01 Oct 2020 17:40:49
User entered 'Day 5'	System	01 Oct 2020 17:40:49

FDA-CBER-2022-1614-1779319

US3472001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:42:27
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 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-05T19:32:22', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'c68af087-6c63-4e23-b153-3df632ef2716'	(b) (4), (b) (6) System	05 Oct 2020 23:32:38
User entered 'None (1)'	System	05 Oct 2020 23:32:38

FDA-CBER-2022-1614-1779320

US3472001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:42:27
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-05T19:32:25', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'c68af087-6c63-4e23-b153-3df632ef2716'	(b) (4), (b) (6) System	05 Oct 2020 23:32:38
User entered 'No (N)'	System	05 Oct 2020 23:32:38

FDA-CBER-2022-1614-1779321

US3472001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:42:27
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-05T19:32:28', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'c68af087-6c63-4e23-b153-3df632ef2716'	(b) (4), (b) (6) System	05 Oct 2020 23:32:38
User entered 'No (N)'	System	05 Oct 2020 23:32:38

FDA-CBER-2022-1614-1779322

US3472001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:42:27
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 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-05T19:32:30', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'c68af087-6c63-4e23-b153-3df632ef2716'	(b) (4), (b) (6) System	05 Oct 2020 23:32:38
User entered 'None (1)'	System	05 Oct 2020 23:32:38

FDA-CBER-2022-1614-1779323

US3472001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:42:27
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-05T19:32:35', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'c68af087-6c63-4e23-b153-3df632ef2716'	(b) (4), (b) (6) System	05 Oct 2020 23:32:38
User entered '05 Oct 2020 19:32'	System	05 Oct 2020 23:32:38

FDA-CBER-2022-1614-1779324

US3472001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:42:27
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
User entered '05 Oct 2020 12:00'	(b) (4), (b) (6) System	01 Oct 2020 17:40:49

FDA-CBER-2022-1614-1779325

US3472001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 17:42:27
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
User entered '06 Oct 2020 11:59'	(b) (4), (b) (6) System	01 Oct 2020 17:40:49

FDA-CBER-2022-1614-1779326

US3472001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:42:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
Data entry locked.	System	01 Oct 2020 17:40:49
User entered 'Day 6'	System	01 Oct 2020 17:40:49

FDA-CBER-2022-1614-1779327

US3472001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:42:27
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 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-06T20:32:23', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '2cf829f8-f494-4ea9-8642-26ab5db5dbce'	(b) (4), (b) (6) System	07 Oct 2020 00:32:38
User entered 'None (1)'	System	07 Oct 2020 00:32:38

FDA-CBER-2022-1614-1779328

US3472001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:42:27
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-06T20:32:26', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '2cf829f8-f494-4ea9-8642-26ab5db5dbce'	(b) (4), (b) (6) System	07 Oct 2020 00:32:38
User entered 'No (N)'	System	07 Oct 2020 00:32:38

FDA-CBER-2022-1614-1779329

US3472001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:42:27
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-06T20:32:29', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '2cf829f8-f494-4ea9-8642-26ab5db5dbce'	(b) (4), (b) (6) System	07 Oct 2020 00:32:38
User entered 'No (N)'	System	07 Oct 2020 00:32:38

FDA-CBER-2022-1614-1779330

US3472001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:42:27
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 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-06T20:32:31', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '2cf829f8-f494-4ea9-8642-26ab5db5dbce'	(b) (4), (b) (6) System	07 Oct 2020 00:32:38
User entered 'None (1)'	System	07 Oct 2020 00:32:38

FDA-CBER-2022-1614-1779331

US3472001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:42:27
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-06T20:32:35', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '2cf829f8-f494-4ea9-8642-26ab5db5dbce'	System	07 Oct 2020 00:32:38
User entered '06 Oct 2020 20:32'	System	07 Oct 2020 00:32:38

FDA-CBER-2022-1614-1779332

US3472001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:42:27
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
User entered '06 Oct 2020 12:00'	(b) (4), (b) (6) System	01 Oct 2020 17:40:49

FDA-CBER-2022-1614-1779333

US3472001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 17:42:27
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
User entered '07 Oct 2020 11:59'	(b) (4), (b) (6) System	01 Oct 2020 17:40:49

FDA-CBER-2022-1614-1779334

US3472001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:42:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
Data entry locked.	System	01 Oct 2020 17:40:49
User entered 'Day 7'	System	01 Oct 2020 17:40:49

FDA-CBER-2022-1614-1779335

US3472001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:42:27
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 01:17:24
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-07T20:27:05', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'a4912e95-fb3f-4af6-aa1f-14f9e5838a07'	System	08 Oct 2020 00:27:27
User entered 'None (1)'	System	08 Oct 2020 00:27:27

FDA-CBER-2022-1614-1779336

US3472001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:42:27
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-07T20:27:12', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'a4912e95-fb3f-4af6-aa1f-14f9e5838a07'	(b) (4), (b) (6) System	08 Oct 2020 00:27:27
User entered 'No (N)'	System	08 Oct 2020 00:27:27

FDA-CBER-2022-1614-1779337

US3472001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:42:27
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-07T20:27:15', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'a4912e95-fb3f-4af6-aa1f-14f9e5838a07'	System	08 Oct 2020 00:27:27
User entered 'No (N)'	System	08 Oct 2020 00:27:27

FDA-CBER-2022-1614-1779338

US3472001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:42:27
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 01:17:24
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-07T20:27:18', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'a4912e95-fb3f-4af6-aa1f-14f9e5838a07'	System	08 Oct 2020 00:27:27
User entered 'None (1)'	System	08 Oct 2020 00:27:27

FDA-CBER-2022-1614-1779339

US3472001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:42:27
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-07T20:27:24', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'a4912e95-fb3f-4af6-aa1f-14f9e5838a07'	System	08 Oct 2020 00:27:27
User entered '07 Oct 2020 20:27'	System	08 Oct 2020 00:27:27

FDA-CBER-2022-1614-1779340

US3472001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:42:27
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
User entered '07 Oct 2020 12:00'	(b) (4), (b) (6) System	01 Oct 2020 17:40:49

FDA-CBER-2022-1614-1779341

US3472001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 17:42:27
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
User entered '08 Oct 2020 11:59'	(b) (4), (b) (6) System	01 Oct 2020 17:40:49

FDA-CBER-2022-1614-1779342

US3472001
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:42:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
Data entry locked.	System	01 Oct 2020 17:40:49
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Oct 2020 17:40:49

FDA-CBER-2022-1614-1779343

US3472001
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:42:27
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-01T14:11:29', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'b26b18ad-a63b-4ef6-a59f-9bde8dc39ee8'	(b) (4), (b) (6) System	01 Oct 2020 18:11:53
User entered 'None (0)'	System	01 Oct 2020 18:11:53

FDA-CBER-2022-1614-1779344

US3472001
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:42:27
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-01T14:11:33', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'b26b18ad-a63b-4ef6-a59f-9bde8dc39ee8'	(b) (4), (b) (6) System	01 Oct 2020 18:11:53
User entered 'None (0)'	System	01 Oct 2020 18:11:53

FDA-CBER-2022-1614-1779345

US3472001
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:42:27
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-01T14:11:35', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'b26b18ad-a63b-4ef6-a59f-9bde8dc39ee8'	(b) (4), (b) (6) System	01 Oct 2020 18:11:53
User entered 'None (0)'	System	01 Oct 2020 18:11:53

FDA-CBER-2022-1614-1779346

US3472001
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:42:27
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-01T14:11:36', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'b26b18ad-a63b-4ef6-a59f-9bde8dc39ee8'	(b) (4), (b) (6) System	01 Oct 2020 18:11:53
User entered 'None (0)'	System	01 Oct 2020 18:11:53

FDA-CBER-2022-1614-1779347

US3472001
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:42:27
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-01T14:11:40', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'b26b18ad-a63b-4ef6-a59f-9bde8dc39ee8'	(b) (4), (b) (6) System	01 Oct 2020 18:11:53
User entered 'None (0)'	System	01 Oct 2020 18:11:53

FDA-CBER-2022-1614-1779348

US3472001
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:42:27
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-01T14:11:42', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'b26b18ad-a63b-4ef6-a59f-9bde8dc39ee8'	(b) (4), (b) (6) System	01 Oct 2020 18:11:53
User entered 'None (0)'	System	01 Oct 2020 18:11:53

FDA-CBER-2022-1614-1779349

US3472001
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:42:27
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 01:17:24
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-01T14:11:45', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'b26b18ad-a63b-4ef6-a59f-9bde8dc39ee8'	System	01 Oct 2020 18:11:53
User entered 'No (N)'	System	01 Oct 2020 18:11:53

FDA-CBER-2022-1614-1779350

US3472001
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:42:27
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-01T14:11:49', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'b26b18ad-a63b-4ef6-a59f-9bde8dc39ee8'	System	01 Oct 2020 18:11:53
User entered '01 Oct 2020 14:11'	System	01 Oct 2020 18:11:53

FDA-CBER-2022-1614-1779351

US3472001
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:42:27
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
User entered '01 Oct 2020 13:58'	(b) (4), (b) (6) System	01 Oct 2020 17:40:49

FDA-CBER-2022-1614-1779352

US3472001
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 17:42:27
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
User entered '01 Oct 2020 16:28'	(b) (4), (b) (6) System	01 Oct 2020 17:40:49

FDA-CBER-2022-1614-1779353

US3472001
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:42:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
Data entry locked.	System	01 Oct 2020 17:40:49
User entered 'Day 1, after vaccination (at home)'	System	01 Oct 2020 17:40:49

FDA-CBER-2022-1614-1779354

US3472001
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:42:27
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-01T22:34:44', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '38d93768-58df-4583-99eb-bcb1d6812d60'	(b) (4), (b) (6) System	02 Oct 2020 02:35:09
User entered 'None (0)'	System	02 Oct 2020 02:35:09

FDA-CBER-2022-1614-1779355

US3472001
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:42:27
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-01T22:34:47', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '38d93768-58df-4583-99eb-bcb1d6812d60'	(b) (4), (b) (6) System	02 Oct 2020 02:35:09
User entered 'None (0)'	System	02 Oct 2020 02:35:09

FDA-CBER-2022-1614-1779356

US3472001
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:42:27
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-01T22:34:49', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '38d93768-58df-4583-99eb-bcb1d6812d60'	(b) (4), (b) (6) System	02 Oct 2020 02:35:09
User entered 'None (0)'	System	02 Oct 2020 02:35:09

FDA-CBER-2022-1614-1779357

US3472001
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:42:27
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-01T22:34:52', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '38d93768-58df-4583-99eb-bcb1d6812d60'	(b) (4), (b) (6) System	02 Oct 2020 02:35:09
User entered 'None (0)'	System	02 Oct 2020 02:35:09

FDA-CBER-2022-1614-1779358

US3472001
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:42:27
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-01T22:34:55', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '38d93768-58df-4583-99eb-bcb1d6812d60'	(b) (4), (b) (6) System	02 Oct 2020 02:35:09
User entered 'None (0)'	System	02 Oct 2020 02:35:09

FDA-CBER-2022-1614-1779359

US3472001
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:42:27
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-01T22:34:57', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '38d93768-58df-4583-99eb-bcb1d6812d60'	(b) (4), (b) (6) System	02 Oct 2020 02:35:09
User entered 'None (0)'	System	02 Oct 2020 02:35:09

FDA-CBER-2022-1614-1779360

US3472001
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:42:27
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 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-01T22:35:01', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '38d93768-58df-4583-99eb-bcb1d6812d60'	(b) (4), (b) (6) System	02 Oct 2020 02:35:09
User entered 'No (N)'	System	02 Oct 2020 02:35:09

FDA-CBER-2022-1614-1779361

US3472001
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:42:27
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-01T22:35:05', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '38d93768-58df-4583-99eb-bcb1d6812d60'	(b) (4), (b) (6) System	02 Oct 2020 02:35:09
User entered '01 Oct 2020 22:35'	System	02 Oct 2020 02:35:09

FDA-CBER-2022-1614-1779362

US3472001
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:42:27
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
User entered '01 Oct 2020 17:23'	(b) (4), (b) (6) System	01 Oct 2020 17:40:49

FDA-CBER-2022-1614-1779363

US3472001
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 17:42:27
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
User entered '02 Oct 2020 11:59'	(b) (4), (b) (6) System	01 Oct 2020 17:40:49

FDA-CBER-2022-1614-1779364

US3472001
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:42:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
Data entry locked.	System	01 Oct 2020 17:40:49
User entered 'Day 2'	System	01 Oct 2020 17:40:49

FDA-CBER-2022-1614-1779365

US3472001
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:42:27
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-02T18:15:56', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '43fdccc7-58d1-4cb0-99fd-2cec0e15226c'	(b) (4), (b) (6) System	02 Oct 2020 22:16:22
User entered 'None (0)'	System	02 Oct 2020 22:16:22

FDA-CBER-2022-1614-1779366

US3472001
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:42:27
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-02T18:15:58', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '43fdccc7-58d1-4cb0-99fd-2cec0e15226c'	(b) (4), (b) (6) System	02 Oct 2020 22:16:22
User entered 'None (0)'	System	02 Oct 2020 22:16:22

FDA-CBER-2022-1614-1779367

US3472001
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:42:27
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-02T18:16:00', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '43fdccc7-58d1-4cb0-99fd-2cec0e15226c'	(b) (4), (b) (6) System	02 Oct 2020 22:16:22
User entered 'None (0)'	System	02 Oct 2020 22:16:22

FDA-CBER-2022-1614-1779368

US3472001
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:42:27
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-02T18:16:04', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '43fdccc7-58d1-4cb0-99fd-2cec0e15226c'	(b) (4), (b) (6) System	02 Oct 2020 22:16:22
User entered 'None (0)'	System	02 Oct 2020 22:16:22

FDA-CBER-2022-1614-1779369

US3472001
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:42:27
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-02T18:16:07', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '43fdccc7-58d1-4cb0-99fd-2cec0e15226c'	(b) (4), (b) (6) System	02 Oct 2020 22:16:22
User entered 'None (0)'	System	02 Oct 2020 22:16:22

FDA-CBER-2022-1614-1779370

US3472001
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:42:27
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-02T18:16:10', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '43fdccc7-58d1-4cb0-99fd-2cec0e15226c'	(b) (4), (b) (6) System	02 Oct 2020 22:16:22
User entered 'None (0)'	System	02 Oct 2020 22:16:22

FDA-CBER-2022-1614-1779371

US3472001
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:42:27
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 01:17:24
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-02T18:16:13', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '43fdccc7-58d1-4cb0-99fd-2cec0e15226c'	System	02 Oct 2020 22:16:22
User entered 'No (N)'	System	02 Oct 2020 22:16:22

FDA-CBER-2022-1614-1779372

US3472001
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:42:27
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-02T18:16:19', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '43fdccc7-58d1-4cb0-99fd-2cec0e15226c'	System	02 Oct 2020 22:16:22
User entered '02 Oct 2020 18:16'	System	02 Oct 2020 22:16:22

FDA-CBER-2022-1614-1779373

US3472001
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:42:27
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
User entered '02 Oct 2020 12:00'	(b) (4), (b) (6) System	01 Oct 2020 17:40:49

FDA-CBER-2022-1614-1779374

US3472001
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 17:42:27
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
User entered '03 Oct 2020 11:59'	(b) (4), (b) (6) System	01 Oct 2020 17:40:49

FDA-CBER-2022-1614-1779375

US3472001
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:42:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
Data entry locked.	System	01 Oct 2020 17:40:49
User entered 'Day 3'	System	01 Oct 2020 17:40:49

FDA-CBER-2022-1614-1779376

US3472001
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:42:27
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-03T19:11:41', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'c3921de2-61f7-47d5-a156-656e1e2c5527'	(b) (4), (b) (6) System	03 Oct 2020 23:12:03
User entered 'None (0)'	System	03 Oct 2020 23:12:03

FDA-CBER-2022-1614-1779377

US3472001
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:42:27
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-03T19:11:43', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'c3921de2-61f7-47d5-a156-656e1e2c5527'	(b) (4), (b) (6) System	03 Oct 2020 23:12:03
User entered 'None (0)'	System	03 Oct 2020 23:12:03

FDA-CBER-2022-1614-1779378

US3472001
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:42:27
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-03T19:11:45', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'c3921de2-61f7-47d5-a156-656e1e2c5527'	(b) (4), (b) (6) System	03 Oct 2020 23:12:03
User entered 'None (0)'	System	03 Oct 2020 23:12:03

FDA-CBER-2022-1614-1779379

US3472001
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:42:27
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-03T19:11:47', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'c3921de2-61f7-47d5-a156-656e1e2c5527'	(b) (4), (b) (6) System	03 Oct 2020 23:12:03
User entered 'None (0)'	System	03 Oct 2020 23:12:03

FDA-CBER-2022-1614-1779380

US3472001
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:42:27
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-03T19:11:48', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'c3921de2-61f7-47d5-a156-656e1e2c5527'	System	03 Oct 2020 23:12:03
User entered 'None (0)'	System	03 Oct 2020 23:12:03

FDA-CBER-2022-1614-1779381

US3472001
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:42:27
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-03T19:11:50', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'c3921de2-61f7-47d5-a156-656e1e2c5527'	(b) (4), (b) (6) System	03 Oct 2020 23:12:03
User entered 'None (0)'	System	03 Oct 2020 23:12:03

FDA-CBER-2022-1614-1779382

US3472001
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:42:27
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 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-03T19:11:55', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'c3921de2-61f7-47d5-a156-656e1e2c5527'	(b) (4), (b) (6) System	03 Oct 2020 23:12:03
User entered 'No (N)'	System	03 Oct 2020 23:12:03

FDA-CBER-2022-1614-1779383

US3472001
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:42:27
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-03T19:11:59', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'c3921de2-61f7-47d5-a156-656e1e2c5527'	(b) (4), (b) (6) System	03 Oct 2020 23:12:03
User entered '03 Oct 2020 19:11'	System	03 Oct 2020 23:12:03

FDA-CBER-2022-1614-1779384

US3472001
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:42:27
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
User entered '03 Oct 2020 12:00'	(b) (4), (b) (6) System	01 Oct 2020 17:40:49

FDA-CBER-2022-1614-1779385

US3472001
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 17:42:27
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
User entered '04 Oct 2020 11:59'	(b) (4), (b) (6) System	01 Oct 2020 17:40:49

FDA-CBER-2022-1614-1779386

US3472001
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:42:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
Data entry locked.	System	01 Oct 2020 17:40:49
User entered 'Day 4'	System	01 Oct 2020 17:40:49

FDA-CBER-2022-1614-1779387

US3472001
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:42:27
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-04T19:47:48', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '7f74cb1b-d933-4037-96b0-86e5100b151d'	(b) (4), (b) (6) System	04 Oct 2020 23:48:13
User entered 'None (0)'	System	04 Oct 2020 23:48:13

FDA-CBER-2022-1614-1779388

US3472001
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:42:27
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-04T19:47:53', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '7f74cb1b-d933-4037-96b0-86e5100b151d'	(b) (4), (b) (6) System	04 Oct 2020 23:48:13
User entered 'None (0)'	System	04 Oct 2020 23:48:13

FDA-CBER-2022-1614-1779389

US3472001
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:42:27
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-04T19:47:56', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '7f74cb1b-d933-4037-96b0-86e5100b151d'	(b) (4), (b) (6) System	04 Oct 2020 23:48:13
User entered 'None (0)'	System	04 Oct 2020 23:48:13

FDA-CBER-2022-1614-1779390

US3472001
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:42:27
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-04T19:47:58', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '7f74cb1b-d933-4037-96b0-86e5100b151d'	(b) (4), (b) (6) System	04 Oct 2020 23:48:13
User entered 'None (0)'	System	04 Oct 2020 23:48:13

FDA-CBER-2022-1614-1779391

US3472001
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:42:27
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-04T19:48:01', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '7f74cb1b-d933-4037-96b0-86e5100b151d'	(b) (4), (b) (6) System	04 Oct 2020 23:48:13
User entered 'None (0)'	System	04 Oct 2020 23:48:13

FDA-CBER-2022-1614-1779392

US3472001
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:42:27
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-04T19:48:03', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '7f74cb1b-d933-4037-96b0-86e5100b151d'	(b) (4), (b) (6) System	04 Oct 2020 23:48:13
User entered 'None (0)'	System	04 Oct 2020 23:48:13

FDA-CBER-2022-1614-1779393

US3472001
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:42:27
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 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-04T19:48:06', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '7f74cb1b-d933-4037-96b0-86e5100b151d'	(b) (4), (b) (6) System	04 Oct 2020 23:48:13
User entered 'No (N)'	System	04 Oct 2020 23:48:13

FDA-CBER-2022-1614-1779394

US3472001
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:42:27
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-04T19:48:11', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '7f74cb1b-d933-4037-96b0-86e5100b151d'	(b) (4), (b) (6) System	04 Oct 2020 23:48:13
User entered '04 Oct 2020 19:48'	System	04 Oct 2020 23:48:13

FDA-CBER-2022-1614-1779395

US3472001
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:42:27
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
User entered '04 Oct 2020 12:00'	(b) (4), (b) (6) System	01 Oct 2020 17:40:49

FDA-CBER-2022-1614-1779396

US3472001
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 17:42:27
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
User entered '05 Oct 2020 11:59'	(b) (4), (b) (6) System	01 Oct 2020 17:40:49

FDA-CBER-2022-1614-1779397

US3472001
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:42:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
Data entry locked.	System	01 Oct 2020 17:40:49
User entered 'Day 5'	System	01 Oct 2020 17:40:49

FDA-CBER-2022-1614-1779398

US3472001
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:42:27
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-05T19:32:40', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '67ee6d8f-443d-4b54-9634-3aacdb25a811'	(b) (4), (b) (6) System	05 Oct 2020 23:33:05
User entered 'None (0)'	System	05 Oct 2020 23:33:05

FDA-CBER-2022-1614-1779399

US3472001
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:42:27
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-05T19:32:42', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '67ee6d8f-443d-4b54-9634-3aacdb25a811'	(b) (4), (b) (6) System	05 Oct 2020 23:33:05
User entered 'None (0)'	System	05 Oct 2020 23:33:05

FDA-CBER-2022-1614-1779400

US3472001
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:42:27
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-05T19:32:44', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '67ee6d8f-443d-4b54-9634-3aacdb25a811'	(b) (4), (b) (6) System	05 Oct 2020 23:33:05
User entered 'None (0)'	System	05 Oct 2020 23:33:05

FDA-CBER-2022-1614-1779401

US3472001
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:42:27
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-05T19:32:46', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '67ee6d8f-443d-4b54-9634-3aacdb25a811'	(b) (4), (b) (6) System	05 Oct 2020 23:33:05
User entered 'None (0)'	System	05 Oct 2020 23:33:05

FDA-CBER-2022-1614-1779402

US3472001
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:42:27
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-05T19:32:48', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '67ee6d8f-443d-4b54-9634-3aacdb25a811'	(b) (4), (b) (6) System	05 Oct 2020 23:33:05
User entered 'None (0)'	System	05 Oct 2020 23:33:05

FDA-CBER-2022-1614-1779403

US3472001
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:42:27
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-05T19:32:50', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '67ee6d8f-443d-4b54-9634-3aacdb25a811'	(b) (4), (b) (6) System	05 Oct 2020 23:33:05
User entered 'None (0)'	System	05 Oct 2020 23:33:05

FDA-CBER-2022-1614-1779404

US3472001
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:42:27
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 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-05T19:32:55', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '67ee6d8f-443d-4b54-9634-3aacdb25a811'	(b) (4), (b) (6) System	05 Oct 2020 23:33:05
User entered 'No (N)'	System	05 Oct 2020 23:33:05

FDA-CBER-2022-1614-1779405

US3472001
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:42:27
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-05T19:33:01', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '67ee6d8f-443d-4b54-9634-3aacdb25a811'	(b) (4), (b) (6) System	05 Oct 2020 23:33:05
User entered '05 Oct 2020 19:33'	System	05 Oct 2020 23:33:05

FDA-CBER-2022-1614-1779406

US3472001
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:42:27
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
User entered '05 Oct 2020 12:00'	(b) (4), (b) (6) System	01 Oct 2020 17:40:49

FDA-CBER-2022-1614-1779407

US3472001
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 17:42:27
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
User entered '06 Oct 2020 11:59'	(b) (4), (b) (6) System	01 Oct 2020 17:40:49

FDA-CBER-2022-1614-1779408

US3472001
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:42:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
Data entry locked.	System	01 Oct 2020 17:40:49
User entered 'Day 6'	System	01 Oct 2020 17:40:49

FDA-CBER-2022-1614-1779409

US3472001
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:42:27
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-06T20:32:38', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '7d80665b-b860-442a-b315-1d043b30e420'	(b) (4), (b) (6) System	07 Oct 2020 00:33:10
User entered 'None (0)'	System	07 Oct 2020 00:33:10

FDA-CBER-2022-1614-1779410

US3472001
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:42:27
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-06T20:32:40', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '7d80665b-b860-442a-b315-1d043b30e420'	(b) (4), (b) (6) System	07 Oct 2020 00:33:10
User entered 'None (0)'	System	07 Oct 2020 00:33:10

FDA-CBER-2022-1614-1779411

US3472001
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:42:27
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-06T20:32:42', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '7d80665b-b860-442a-b315-1d043b30e420'	(b) (4), (b) (6) System	07 Oct 2020 00:33:10
User entered 'None (0)'	System	07 Oct 2020 00:33:10

FDA-CBER-2022-1614-1779412

US3472001
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:42:27
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-06T20:32:43', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '7d80665b-b860-442a-b315-1d043b30e420'	(b) (4), (b) (6) System	07 Oct 2020 00:33:10
User entered 'None (0)'	System	07 Oct 2020 00:33:10

FDA-CBER-2022-1614-1779413

US3472001
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:42:27
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-06T20:32:47', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '7d80665b-b860-442a-b315-1d043b30e420'	(b) (4), (b) (6) System	07 Oct 2020 00:33:10
User entered 'None (0)'	System	07 Oct 2020 00:33:10

FDA-CBER-2022-1614-1779414

US3472001
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:42:27
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-06T20:32:48', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '7d80665b-b860-442a-b315-1d043b30e420'	(b) (4), (b) (6) System	07 Oct 2020 00:33:10
User entered 'None (0)'	System	07 Oct 2020 00:33:10

FDA-CBER-2022-1614-1779415

US3472001
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:42:27
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 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-06T20:32:51', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '7d80665b-b860-442a-b315-1d043b30e420'	(b) (4), (b) (6) System	07 Oct 2020 00:33:10
User entered 'No (N)'	System	07 Oct 2020 00:33:10

FDA-CBER-2022-1614-1779416

US3472001
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:42:27
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-06T20:32:56', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '7d80665b-b860-442a-b315-1d043b30e420'	(b) (4), (b) (6) System	07 Oct 2020 00:33:10
User entered '06 Oct 2020 20:32'	System	07 Oct 2020 00:33:10

FDA-CBER-2022-1614-1779417

US3472001
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:42:27
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
User entered '06 Oct 2020 12:00'	(b) (4), (b) (6) System	01 Oct 2020 17:40:49

FDA-CBER-2022-1614-1779418

US3472001
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 17:42:27
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
User entered '07 Oct 2020 11:59'	(b) (4), (b) (6) System	01 Oct 2020 17:40:49

FDA-CBER-2022-1614-1779419

US3472001
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:42:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
Data entry locked.	System	01 Oct 2020 17:40:49
User entered 'Day 7'	System	01 Oct 2020 17:40:49

FDA-CBER-2022-1614-1779420

US3472001
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:42:27
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-07T20:27:28', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'e0bac0ef-a179-46ea-a095-8be44d010b1e'	(b) (4), (b) (6) System	08 Oct 2020 00:27:56
User entered 'None (0)'	System	08 Oct 2020 00:27:56

FDA-CBER-2022-1614-1779421

US3472001
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:42:27
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-07T20:27:30', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'e0bac0ef-a179-46ea-a095-8be44d010b1e'	(b) (4), (b) (6) System	08 Oct 2020 00:27:56
User entered 'None (0)'	System	08 Oct 2020 00:27:56

FDA-CBER-2022-1614-1779422

US3472001
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:42:27
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-07T20:27:32', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'e0bac0ef-a179-46ea-a095-8be44d010b1e'	(b) (4), (b) (6) System	08 Oct 2020 00:27:56
User entered 'None (0)'	System	08 Oct 2020 00:27:56

FDA-CBER-2022-1614-1779423

US3472001
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:42:27
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-07T20:27:35', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'e0bac0ef-a179-46ea-a095-8be44d010b1e'	(b) (4), (b) (6) System	08 Oct 2020 00:27:56
User entered 'None (0)'	System	08 Oct 2020 00:27:56

FDA-CBER-2022-1614-1779424

US3472001
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:42:27
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-07T20:27:39', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'e0bac0ef-a179-46ea-a095-8be44d010b1e'	(b) (4), (b) (6) System	08 Oct 2020 00:27:56
User entered 'None (0)'	System	08 Oct 2020 00:27:56

FDA-CBER-2022-1614-1779425

US3472001
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:42:27
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-07T20:27:41', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'e0bac0ef-a179-46ea-a095-8be44d010b1e'	(b) (4), (b) (6) System	08 Oct 2020 00:27:56
User entered 'None (0)'	System	08 Oct 2020 00:27:56

FDA-CBER-2022-1614-1779426

US3472001
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:42:27
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 01:17:24
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-07T20:27:48', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'e0bac0ef-a179-46ea-a095-8be44d010b1e'	System	08 Oct 2020 00:27:56
User entered 'No (N)'	System	08 Oct 2020 00:27:56

FDA-CBER-2022-1614-1779427

US3472001
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:42:27
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-07T20:27:54', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'e0bac0ef-a179-46ea-a095-8be44d010b1e'	(b) (4), (b) (6) System	08 Oct 2020 00:27:56
User entered '07 Oct 2020 20:27'	System	08 Oct 2020 00:27:56

FDA-CBER-2022-1614-1779428

US3472001
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:42:27
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
User entered '07 Oct 2020 12:00'	(b) (4), (b) (6) System	01 Oct 2020 17:40:49

FDA-CBER-2022-1614-1779429

US3472001
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 17:42:27
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
User entered '08 Oct 2020 11:59'	(b) (4), (b) (6) System	01 Oct 2020 17:40:49

FDA-CBER-2022-1614-1779430

US3472001
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:42:27
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 18:37:17

FDA-CBER-2022-1614-1779431

US3472001
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:42:27
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
User entered '8 Oct 2020'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 18:37:17

FDA-CBER-2022-1614-1779432

US3472001
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:42:27
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 18:37:17

FDA-CBER-2022-1614-1779433

US3472001
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:42:27
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 18:37:17

FDA-CBER-2022-1614-1779434

US3472001
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:42:27
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 18:37:24

FDA-CBER-2022-1614-1779435

US3472001
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:42:27
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered '1'	System	08 Oct 2020 18:37:24

FDA-CBER-2022-1614-1779436

US3472001
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:42:27
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 19:16:32

FDA-CBER-2022-1614-1779437

US3472001
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:42:27
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
User entered '15 Oct 2020'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 19:16:32

FDA-CBER-2022-1614-1779438

US3472001
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:42:27
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 19:16:32

FDA-CBER-2022-1614-1779439

US3472001
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:42:27
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 19:16:32

FDA-CBER-2022-1614-1779440

US3472001
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:42:27
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 19:16:36

FDA-CBER-2022-1614-1779441

US3472001
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:42:27
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered '1'	System	15 Oct 2020 19:16:36

FDA-CBER-2022-1614-1779442

US3472001
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:42:27
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 19:45:41

FDA-CBER-2022-1614-1779443

US3472001
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:42:27
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
User entered '22 Oct 2020'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 19:45:41

FDA-CBER-2022-1614-1779444

US3472001
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:42:27
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 19:45:41

FDA-CBER-2022-1614-1779445

US3472001
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:42:27
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 19:45:41

FDA-CBER-2022-1614-1779446

US3472001
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:42:27
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 19:45:54

FDA-CBER-2022-1614-1779447

US3472001
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:42:27
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered '1'	System	22 Oct 2020 19:45:54

FDA-CBER-2022-1614-1779448

US3472001
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:42:27
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:28
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
User entered 'Yes (Y)'	Christopher Chianese (b) (4)	26 Oct 2020 12:52:31

FDA-CBER-2022-1614-1779449

US3472001
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:42:27
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:28
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
User entered '26 Oct 2020'	Christopher Chianese (b) (4)	26 Oct 2020 12:52:31

FDA-CBER-2022-1614-1779450

US3472001
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:42:27
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 01:44:28
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
User entered 'Clinic (Clinic)'	Christopher Chianese (b) (4)	26 Oct 2020 12:52:31

FDA-CBER-2022-1614-1779451

US3472001
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 17:42:27
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:28
User entered 'VISIT3'	System	26 Oct 2020 12:52:31

FDA-CBER-2022-1614-1779452

US3472001
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:42:27
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:28
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 02:06:51

FDA-CBER-2022-1614-1779453

US3472001
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:42:27
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:28
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
User entered '26 Oct 2020'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 02:06:51

FDA-CBER-2022-1614-1779454

US3472001
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:42:27
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:28
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
User entered '08:11'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 02:06:51

FDA-CBER-2022-1614-1779455

US3472001
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:42:27
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:28
User entered '26 Oct 2020 08:11'	System	27 Oct 2020 02:06:51

FDA-CBER-2022-1614-1779456

US3472001
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:42:27
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:28
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
User entered '36.2' C	(b) (4) (b) (4), (b) (6)	27 Oct 2020 02:06:51

FDA-CBER-2022-1614-1779457

US3472001
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:42:27
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:28
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 02:06:51

FDA-CBER-2022-1614-1779458

US3472001
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:42:27
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:28
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 02:06:51

FDA-CBER-2022-1614-1779459

US3472001
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:42:27
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:28
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
User entered '71'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 02:06:51

FDA-CBER-2022-1614-1779460

US3472001
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:42:27
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:28
User entered 'bpm'	System	27 Oct 2020 02:06:51

FDA-CBER-2022-1614-1779461

US3472001
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:42:27
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:28
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
User entered '18'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 02:06:51

FDA-CBER-2022-1614-1779462

US3472001
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:42:27
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:28
User entered 'breaths/min'	System	27 Oct 2020 02:06:51

FDA-CBER-2022-1614-1779463

US3472001
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:42:27
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:28
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
User entered '115'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 02:06:51

FDA-CBER-2022-1614-1779464

US3472001
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:42:27
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:28
User entered 'mmHg'	System	27 Oct 2020 02:06:51

FDA-CBER-2022-1614-1779465

US3472001
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:42:27
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:28
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
User entered '72'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 02:06:51

FDA-CBER-2022-1614-1779466

US3472001
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:42:27
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:28
User entered 'mmHg'	System	27 Oct 2020 02:06:51

FDA-CBER-2022-1614-1779467

US3472001
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:42:27
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:28

FDA-CBER-2022-1614-1779468

US3472001
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 17:42:27
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:28

FDA-CBER-2022-1614-1779469

US3472001
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 17:42:27
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:28
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 02:07:23

FDA-CBER-2022-1614-1779470

US3472001
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 17:42:27
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:28
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 02:07:23

FDA-CBER-2022-1614-1779471

US3472001
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 17:42:27
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 02:08:05

FDA-CBER-2022-1614-1779472

US3472001
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 17:42:27
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 26Oct2020 is recorded under Visit 3 Day 57 visit in EDC, however the same is reported under Visit 2 Day 29 visit in PPD Central lab. Please reconcile and confirm the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 18:16:25
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 26Oct2020 is recorded under Visit 3 Day 57 visit in EDC, however the same is reported under Visit 2 Day 29 visit in PPD Central lab. Please reconcile and confirm the correct Visit and update if applicable. Else clarify, thank you.' answered with 'Confirming collection was for v2.0. No kits were available, unscheduled kits used per instruction of CRA.' (Site from DM).	Jie Ho (b) (4)	08 Nov 2020 23:07:43
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 26Oct2020 is recorded under Visit 3 Day 57 visit in EDC, however the same is reported under Visit 2 Day 29 visit in PPD Central lab. Please reconcile and confirm the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 21:05:50
User entered '26 Oct 2020'	(b) (4), (b) (6)	27 Oct 2020 02:08:05

US3472001
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 17:42:27
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
User entered '09:35'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 02:08:05

FDA-CBER-2022-1614-1779474

US3472001
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 17:42:27
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered '26 Oct 2020 09:35'	System	27 Oct 2020 02:08:05

FDA-CBER-2022-1614-1779475

US3472001
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:42:27
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 02:08:13

FDA-CBER-2022-1614-1779476

US3472001
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:42:27
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered '1'	System	27 Oct 2020 02:08:13

FDA-CBER-2022-1614-1779477

US3472001
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
Data entry locked.	System	31 Aug 2020 15:27:47
User entered 'Day 64'	System	31 Aug 2020 15:27:47

FDA-CBER-2022-1614-1779478

US3472001

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:27

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 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-31T00:16:36', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '6434fc1d-ebf2-4d2f-98f9-8ba912cbbfea'	(b) (4), (b) (6) System	31 Oct 2020 04:16:55
User entered 'No (N)'	System	31 Oct 2020 04:16:55

US3472001

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:27

Have you been exposed to someone with 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 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-31T00:16:41', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '6434fc1d-ebf2-4d2f-98f9-8ba912cbbfea'	(b) (4), (b) (6) System	31 Oct 2020 04:16:55
User entered 'No (N)'	System	31 Oct 2020 04:16:55

US3472001
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:27
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-10-31T00:16:52', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '6434fc1d-ebf2-4d2f-98f9-8ba912cbbfea'	System	31 Oct 2020 04:16:55
User entered '31 Oct 2020 00:16:52'	System	31 Oct 2020 04:16:55

FDA-CBER-2022-1614-1779481

US3472001
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
Data entry locked.	System	31 Aug 2020 15:27:47
User entered '31 Oct 2020 00:01'	System	31 Aug 2020 15:27:47

FDA-CBER-2022-1614-1779482

US3472001
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
Data entry locked.	System	31 Aug 2020 15:27:47
User entered '04 Nov 2020 23:59'	System	31 Aug 2020 15:27:47

FDA-CBER-2022-1614-1779483

US3472001
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
Data entry locked.	System	31 Aug 2020 15:27:47
User entered 'Day 71'	System	31 Aug 2020 15:27:47

FDA-CBER-2022-1614-1779484

US3472001

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:27

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 01:17:24
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-11-07T01:35:36', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '2d32f4fd-c82e-4bbc-a8a4-09b5d82a7ee8'	System	07 Nov 2020 06:35:54
User entered 'No (N)'	System	07 Nov 2020 06:35:54

US3472001

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:27

Have you been exposed to someone with 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 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-11-07T01:35:45', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '2d32f4fd-c82e-4bbc-a8a4-09b5d82a7ee8'	(b) (4), (b) (6) System	07 Nov 2020 06:35:54
User entered 'No (N)'	System	07 Nov 2020 06:35:54

US3472001
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:27
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-11-07T01:35:52', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '2d32f4fd-c82e-4bbc-a8a4-09b5d82a7ee8'	System	07 Nov 2020 06:35:54
User entered '07 Nov 2020 01:35:52'	System	07 Nov 2020 06:35:54

FDA-CBER-2022-1614-1779487

US3472001
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
Data entry locked.	System	31 Aug 2020 15:27:47
User entered '07 Nov 2020 00:01'	System	31 Aug 2020 15:27:47

FDA-CBER-2022-1614-1779488

US3472001
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
Data entry locked.	System	31 Aug 2020 15:27:47
User entered '11 Nov 2020 23:59'	System	31 Aug 2020 15:27:47

FDA-CBER-2022-1614-1779489

US3472001
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
Data entry locked.	System	31 Aug 2020 15:27:47
User entered 'Day 78'	System	31 Aug 2020 15:27:47

FDA-CBER-2022-1614-1779490

US3472001

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:27

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 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-11-14T00:18:52', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'fc486194-9d42-4144-b4b8-65850ba5f806'	(b) (4), (b) (6) System	14 Nov 2020 05:19:25
User entered 'No (N)'	System	14 Nov 2020 05:19:25

US3472001

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:27

Have you been exposed to someone with 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 01:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-11-14T00:19:03', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'fc486194-9d42-4144-b4b8-65850ba5f806'	(b) (4), (b) (6) System	14 Nov 2020 05:19:25
User entered 'No (N)'	System	14 Nov 2020 05:19:25

US3472001
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:27
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-11-14T00:19:19', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'fc486194-9d42-4144-b4b8-65850ba5f806'	System	14 Nov 2020 05:19:25
User entered '14 Nov 2020 00:19:19'	System	14 Nov 2020 05:19:25

FDA-CBER-2022-1614-1779493

US3472001
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
Data entry locked.	System	31 Aug 2020 15:27:47
User entered '14 Nov 2020 00:01'	System	31 Aug 2020 15:27:47

FDA-CBER-2022-1614-1779494

US3472001
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:17:24
	(b) (4), (b) (6)	
Data entry locked.	System	31 Aug 2020 15:27:47
User entered '18 Nov 2020 23:59'	System	31 Aug 2020 15:27:47

FDA-CBER-2022-1614-1779495

US3472001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:44:38
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 20:44:38

FDA-CBER-2022-1614-1779496

US3472001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:27

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)	28 Apr 2021 01:44:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-11-21T19:44:16', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'd28233f2-771d-4601-a8d5-fcab64a71930'	System	22 Nov 2020 00:44:32
User entered 'No (N)'	System	22 Nov 2020 00:44:32

US3472001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:27

Have you been exposed to someone with 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)	28 Apr 2021 01:44:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-11-21T19:44:21', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'd28233f2-771d-4601-a8d5-fcab64a71930'	System	22 Nov 2020 00:44:32
User entered 'No (N)'	System	22 Nov 2020 00:44:32

US3472001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:27
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-11-21T19:44:28', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: 'd28233f2-771d-4601-a8d5-fcab64a71930'	System	22 Nov 2020 00:44:32
User entered '21 Nov 2020 19:44:28'	System	22 Nov 2020 00:44:32

FDA-CBER-2022-1614-1779499

US3472001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:44:38
Amendment Manager: User entered '18 Nov 2020 00:01'	System	19 Nov 2020 20:44:38

FDA-CBER-2022-1614-1779500

US3472001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:44:38
Amendment Manager: User entered '22 Nov 2020 23:59'	System	19 Nov 2020 20:44:38

FDA-CBER-2022-1614-1779501

US3472001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:27
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:44:38
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 20:44:38

FDA-CBER-2022-1614-1779502

US3472001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:27

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)	28 Apr 2021 01:44:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-11-25T00:02:24', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '12b22b1d-c506-4229-920f-090dccc57190'	System	25 Nov 2020 05:02:48
User entered 'No (N)'	System	25 Nov 2020 05:02:48

US3472001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:42:27

Have you been exposed to someone with 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)	28 Apr 2021 01:44:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-11-25T00:02:28', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '12b22b1d-c506-4229-920f-090dccc57190'	System	25 Nov 2020 05:02:48
User entered 'No (N)'	System	25 Nov 2020 05:02:48

US3472001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:27
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1582E2D6-4A87-497C-A4A9-062154BF5FCE)', Time: '2020-11-25T00:02:34', User OID: 'PatientReportedOutcome (US3472001)', ODM File OID: '12b22b1d-c506-4229-920f-090dccc57190'	System	25 Nov 2020 05:02:48
User entered '25 Nov 2020 00:02:34'	System	25 Nov 2020 05:02:48

US3472001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:27
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:44:38
Amendment Manager: User entered '25 Nov 2020 00:01'	System	19 Nov 2020 20:44:38

FDA-CBER-2022-1614-1779506

US3472001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 17:42:27
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:44:38
Amendment Manager: User entered '29 Nov 2020 23:59'	System	19 Nov 2020 20:44:38

FDA-CBER-2022-1614-1779507

US3472001
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:42:27
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:28:22

FDA-CBER-2022-1614-1779508

US3472001
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:42:27
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
User entered '23 Nov 2020'	(b) (4), (b) (6)	23 Nov 2020 17:28:22

FDA-CBER-2022-1614-1779509

US3472001
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:42:27
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:28:22

US3472001
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:42:27
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
User entered empty.	(b) (4), (b) (6)	23 Nov 2020 17:28:22

US3472001
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:42:27
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Nov 2020 17:28:28
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	13 Nov 2020 04:39:00
Query 'Data is required. Please complete.' answered with 'erroneously entered.' (Site from System).	Jie Ho (b) (4)	28 Oct 2020 19:23:26
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Oct 2020 19:23:15
User entered empty; reason for change Data Entry Error	Jie Ho (b) (4)	28 Oct 2020 19:23:15
User entered 'Yes (Y)'	Jie Ho (b) (4)	28 Oct 2020 19:22:58

FDA-CBER-2022-1614-1779512

US3472001
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:42:27
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered '1'	System	23 Nov 2020 17:28:28
User entered empty.	System	28 Oct 2020 19:23:15
User entered '1'	System	28 Oct 2020 19:22:58

FDA-CBER-2022-1614-1779513

US3472001
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:42:27
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
User entered 'No (N)'	(b) (4), (b) (6)	25 Feb 2021 17:17:18

FDA-CBER-2022-1614-1779514

US3472001
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:42:27
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 17:17:18

FDA-CBER-2022-1614-1779515

US3472001
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:42:27
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 17:17:18

FDA-CBER-2022-1614-1779516

US3472001
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 09 Jun 2021 17:42:27
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
User entered 'This ppt passed away 27NOV2020'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:17:18

FDA-CBER-2022-1614-1779517

US3472001
Folder: Safety Call Day 119 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:42:27
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
User entered 'No (N)'	(b) (4), (b) (6)	25 Feb 2021 17:17:23

US3472001
Folder: Safety Call Day 119 (1)
Form: Continuing
Generated On: 09 Jun 2021 17:42:27
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered empty.	System	25 Feb 2021 17:17:23

FDA-CBER-2022-1614-1779519

US3472001
Folder: Adverse Events
Form: Adverse Events Summary
Generated On: 09 Jun 2021 17:42:27
Did the participant experience any adverse events?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:24:07
User entered 'Yes (Y)' reason for change: Per Query Resolution	(b) (4), (b) (6)	23 Oct 2020 14:27:04
User closed query 'Per CDM: Per previous response, please record as NO just now and update to YES if any AE's occur later.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 10:53:41
Query 'Per CDM: Per previous response, please record as NO just now and update to YES if any AE's occur later.' answered with 'Thank you, response updated.' (Site from DM).	Jie Ho (b) (4)	08 Sep 2020 14:24:02
User entered 'No (N)' reason for change: Per Query Resolution	Jie Ho (b) (4)	08 Sep 2020 14:23:53
User opened query 'Per CDM: Per previous response, please record as NO just now and update to YES if any AE's occur later.' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 08:50:04
User closed query 'Per CDM: Response noted; However a response Yes/No is required for this field. Please update as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 08:50:04
Query 'Per CDM: Response noted; However a response Yes/No is required for this field. Please update as appropriate.' answered with 'Thank you, but AEs may occur throughout the study. Should I mark 'no' for now until an AE is reported and change to 'yes' then?' (Site from DM).	Jie Ho (b) (4)	08 Sep 2020 01:47:02
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	07 Sep 2020 10:33:50
User opened query 'Per CDM: Response noted; However a response Yes/No is required for this field. Please update as appropriate.' (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 10:33:44
Query 'Data is required. Please complete.' answered with 'Erroneously entered data.' (Site from System).	Jie Ho (b) (4)	06 Sep 2020 18:10:57
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Sep 2020 18:10:40
User entered empty.	Jie Ho (b) (4)	06 Sep 2020 18:10:40

FDA-CBER-2022-1614-1779520

US3472001
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:42:27
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19

FDA-CBER-2022-1614-1779521

US3472001
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:42:27
Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:24:16
User coded data point as SOC: Investigations, HLGT: Microbiology and serology investigations, HLT: Virus identification and serology, PT: Hepatitis C antibody positive, LLT: Hepatitis C antibody positive - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Nov 2020 14:10:24
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Nov 2020 14:10:24
Data point term sent to Coder	System	28 Nov 2020 15:50:52
Coding entries removed.	Debora Dunbar (b) (4) (b) (4)	28 Nov 2020 15:50:04
User entered 'POSITIVE HEPATITIS C ANTIBODY' reason for change: Data Entry Error	Debora Dunbar (b) (4) (b) (4)	28 Nov 2020 15:50:04
User coded data point as SOC: Investigations, HLGT: Microbiology and serology investigations, HLT: Virus identification and serology, PT: Hepatitis B antibody positive, LLT: Hepatitis B antibody positive - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Oct 2020 15:16:31
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Oct 2020 15:16:31
Data point term sent to Coder	System	23 Oct 2020 14:28:37
User entered 'Positive hepatitis B antibody'	(b) (4), (b) (6)	23 Oct 2020 14:27:40

US3472001
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:42:27
Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:24:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Oct 2020 14:27:40

FDA-CBER-2022-1614-1779523

US3472001
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:42:27
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:24:16
User entered 'No (N)'	(b) (4), (b) (6)	23 Oct 2020 14:27:40

FDA-CBER-2022-1614-1779524

US3472001
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:42:27
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:24:16
User entered 'No (N)'	(b) (4), (b) (6)	23 Oct 2020 14:27:40

FDA-CBER-2022-1614-1779525

US3472001
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:42:27
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:24:16
User entered '29 Sep 2020'	(b) (4), (b) (6)	23 Oct 2020 14:27:40

FDA-CBER-2022-1614-1779526

US3472001
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:42:27
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:24:16
User entered empty.	(b) (4), (b) (6)	23 Oct 2020 14:27:40

US3472001
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:42:27
AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered empty.	System	23 Oct 2020 14:27:40

FDA-CBER-2022-1614-1779528

US3472001
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:42:27
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:24:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Oct 2020 14:27:40

FDA-CBER-2022-1614-1779529

US3472001
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:42:27
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:24:16
User entered empty.	(b) (4), (b) (6)	23 Oct 2020 14:27:40

FDA-CBER-2022-1614-1779530

US3472001
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:42:27
End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:24:16
User entered empty.	(b) (4), (b) (6)	23 Oct 2020 14:27:40

US3472001
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:42:27
AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered empty.	System	23 Oct 2020 14:27:40

FDA-CBER-2022-1614-1779532

US3472001
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:42:27
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:24:16
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	23 Oct 2020 14:27:40

US3472001
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:42:27
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:24:16
User entered 'No (N)'	(b) (4), (b) (6)	23 Oct 2020 14:27:40

US3472001
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:42:27
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:24:16
User entered '0'	(b) (4), (b) (6)	23 Oct 2020 14:27:40

FDA-CBER-2022-1614-1779535

US3472001
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:42:27
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:24:16
User entered '0'	(b) (4), (b) (6)	23 Oct 2020 14:27:40

US3472001
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:42:27
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:24:16
User entered '0'	(b) (4), (b) (6)	23 Oct 2020 14:27:40

FDA-CBER-2022-1614-1779537

US3472001
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:42:27
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:24:16
User entered empty.	(b) (4), (b) (6)	23 Oct 2020 14:27:40

FDA-CBER-2022-1614-1779538

US3472001
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:42:27
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:24:16
User entered empty.	(b) (4), (b) (6)	23 Oct 2020 14:27:40

FDA-CBER-2022-1614-1779539

US3472001
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:42:27
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:24:16
User entered empty.	(b) (4), (b) (6)	23 Oct 2020 14:27:40

FDA-CBER-2022-1614-1779540

US3472001
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:42:27
Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:24:16
User entered empty.	(b) (4), (b) (6)	23 Oct 2020 14:27:40

US3472001
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:42:27
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:24:16
User entered '0'	(b) (4), (b) (6)	23 Oct 2020 14:27:40

US3472001
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:42:27
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:24:16
User entered '0'	(b) (4), (b) (6)	23 Oct 2020 14:27:40

US3472001
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:42:27
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:24:16
User entered '0'	(b) (4), (b) (6)	23 Oct 2020 14:27:40

US3472001
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:42:27
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:24:16
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	23 Oct 2020 14:27:40

FDA-CBER-2022-1614-1779545

US3472001
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:42:27
Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:24:16
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	23 Oct 2020 14:27:40

FDA-CBER-2022-1614-1779546

US3472001
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:42:27
Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:24:16
User entered 'None (NONE)'	(b) (4), (b) (6)	23 Oct 2020 14:27:40

FDA-CBER-2022-1614-1779547

US3472001
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:42:27
None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:24:16
User entered '1'	(b) (4), (b) (6)	23 Oct 2020 14:27:40

FDA-CBER-2022-1614-1779548

US3472001
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:42:27
Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:24:16
User entered '0'	(b) (4), (b) (6)	23 Oct 2020 14:27:40

FDA-CBER-2022-1614-1779549

US3472001
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:42:27
Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:24:16
User entered '0'	(b) (4), (b) (6)	23 Oct 2020 14:27:40

FDA-CBER-2022-1614-1779550

US3472001
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:42:27
Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:24:16
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	23 Oct 2020 14:27:40

FDA-CBER-2022-1614-1779551

US3472001
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:42:27
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:24:16
User entered empty.	(b) (4), (b) (6)	23 Oct 2020 14:27:40

US3472001
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:42:27
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:24:16
User entered empty.	(b) (4), (b) (6)	23 Oct 2020 14:27:40

FDA-CBER-2022-1614-1779553

US3472001
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:42:27
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered '0'	System	23 Oct 2020 14:27:40

FDA-CBER-2022-1614-1779554

US3472001
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:42:27
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered '1'	System	23 Oct 2020 14:27:40

FDA-CBER-2022-1614-1779555

US3472001
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 17:42:27
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19

FDA-CBER-2022-1614-1779556

US3472001
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:42:27
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:24:16
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:08:20
User entered 'USA-US122-2020-mRNA-1273-P301000004'	System	30 Nov 2020 16:08:00
User entered 'New'	(b) (4), (b) (6)	30 Nov 2020 16:08:00

FDA-CBER-2022-1614-1779557

US3472001
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:42:27
Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Myocardial infarction, LLT: Myocardial infarction - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Mar 2021 11:52:48
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Mar 2021 11:52:48
Data point term sent to Coder	System	03 Mar 2021 13:55:35
DataPoint Un-verified.	(b) (4), (b) (6)	03 Mar 2021 13:54:59
Coding entries removed.	(b) (4), (b) (6)	03 Mar 2021 13:54:59
User entered 'provisional diagnosis only - SUDDEN FATAL EVENT, LIKELY MYOCARDIAL INFARCTION' reason for change: Per Query Resolution	(b) (4), (b) (6)	03 Mar 2021 13:54:59
User closed query 'PV Query: Please update the event term to primary cause of death, once known, and consider splitting event to outline provisional diagnosis and death. If event remains unknown, please update event term to provisional diagnosis only.' (Site from Safety).	(b) (4), (b) (6)	24 Feb 2021 15:45:44
Query 'PV Query: Please update the event term to primary cause of death, once known, and consider splitting event to outline provisional diagnosis and death. If event remains unknown, please update event term to provisional diagnosis only.' answered with 'we are unable to obtain the death certificate and therefore cannot provide this information' (Site from Safety).	(b) (4), (b) (6)	23 Feb 2021 18:00:51
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:24:16
User opened query 'PV Query: Please update the event term to primary cause of death, once known, and consider splitting event to outline provisional diagnosis and death. If event remains unknown, please update event term to provisional diagnosis only.' (Site from Safety).	(b) (4), (b) (6)	04 Jan 2021 17:33:51

US3472001
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:42:27
Adverse event

Audit	User	Time (GMT)
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Myocardial infarction, LLT: Myocardial infarction - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Dec 2020 21:29:19
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Dec 2020 21:29:19
User closed query 'PV Query: Thank you for reporting the event of death. Please note that death is an outcome; please consider updating the event term to the underlying cause of death.' (Site from Safety).	(b) (4), (b) (6)	08 Dec 2020 15:23:50
Data point term sent to Coder	System	07 Dec 2020 21:41:27
Query 'PV Query: Thank you for reporting the event of death. Please note that death is an outcome; please consider updating the event term to the underlying cause of death.' answered with 'Cause of death is currently unknown, we are working on obtaining the death certificate. AE updated to better describe the current information we have. Thank you.' (Site from Safety).	Jie Ho (b) (4)	07 Dec 2020 21:40:41
Coding entries removed.	Jie Ho (b) (4)	07 Dec 2020 21:40:37
User entered 'Sudden fatal event, likely myocardial infarction' reason for change: Per Query Resolution	Jie Ho (b) (4)	07 Dec 2020 21:40:37
User opened query 'PV Query: Thank you for reporting the event of death. Please note that death is an outcome; please consider updating the event term to the underlying cause of death.' (Site from Safety).	(b) (4), (b) (6)	06 Dec 2020 16:58:16
User coded data point as SOC: General disorders and administration site conditions, HLGT: Fatal outcomes, HLT: Death and sudden death, PT: Death, LLT: Death - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Nov 2020 15:05:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Nov 2020 15:05:10
Data point term sent to Coder	System	28 Nov 2020 15:04:47
User entered 'death'	Debora Dunbar (b) (4) (b) (4)	28 Nov 2020 15:04:31

FDA-CBER-2022-1614-1779559

US3472001
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:42:27
Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:24:16
User entered 'No (N)'	Debora Dunbar (b) (4) (b) (4)	28 Nov 2020 15:04:31

US3472001
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:42:27
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:24:16
User entered 'No (N)'	Debora Dunbar (b) (4) (b) (4)	28 Nov 2020 15:04:31

US3472001
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:42:27
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:24:16
User entered 'No (N)'	Debora Dunbar (b) (4) (b) (4)	28 Nov 2020 15:04:31

US3472001
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:42:27
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:24:16
User entered '27 Nov 2020'	Debora Dunbar (b) (4) (b) (4)	28 Nov 2020 15:04:31

FDA-CBER-2022-1614-1779563

US3472001
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:42:27
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:24:16
User entered empty.	Debora Dunbar (b) (4) (b) (4)	28 Nov 2020 15:04:31

FDA-CBER-2022-1614-1779564

US3472001
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:42:27
AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered empty.	System	28 Nov 2020 15:04:31

FDA-CBER-2022-1614-1779565

US3472001
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:42:27
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:24:16
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	28 Nov 2020 15:09:13
User entered 'No (N)' reason for change: Data Entry Error	Debora Dunbar (b) (4) (b) (4)	28 Nov 2020 15:09:13
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	28 Nov 2020 15:06:01
User entered 'Yes (Y)'	Debora Dunbar (b) (4) (b) (4)	28 Nov 2020 15:04:31

FDA-CBER-2022-1614-1779566

US3472001
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:42:27
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:24:16
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	28 Nov 2020 15:06:01
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	28 Nov 2020 15:06:01
User entered '27 Nov 2020' reason for change: Data Entry Error	Debora Dunbar (b) (4) (b) (4)	28 Nov 2020 15:06:01
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	28 Nov 2020 15:04:31
User entered empty.	Debora Dunbar (b) (4) (b) (4)	28 Nov 2020 15:04:31

FDA-CBER-2022-1614-1779567

US3472001
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:42:27
End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:24:16
User entered empty.	Debora Dunbar (b) (4) (b) (4)	28 Nov 2020 15:04:31

US3472001
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:42:27
AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered empty.	System	28 Nov 2020 15:04:31

FDA-CBER-2022-1614-1779569

US3472001
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:42:27
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:24:16
User entered 'Grade 4 (Grade 4)'	Debora Dunbar (b) (4) (b) (4)	28 Nov 2020 15:04:31

FDA-CBER-2022-1614-1779570

US3472001
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:42:27
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:24:16
User entered 'Yes (Y)'	Debora Dunbar (b) (4) (b) (4)	28 Nov 2020 15:04:31

FDA-CBER-2022-1614-1779571

US3472001
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:42:27
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:24:16
User entered '1'	Debora Dunbar (b) (4) (b) (4)	28 Nov 2020 15:04:31

FDA-CBER-2022-1614-1779572

US3472001
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:42:27
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:24:16
User entered '0'	Debora Dunbar (b) (4) (b) (4)	28 Nov 2020 15:04:31

FDA-CBER-2022-1614-1779573

US3472001
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:42:27
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:24:16
User entered '0'	Debora Dunbar (b) (4) (b) (4)	28 Nov 2020 15:04:31

FDA-CBER-2022-1614-1779574

US3472001
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:42:27
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:24:16
User entered empty.	Debora Dunbar (b) (4) (b) (4)	28 Nov 2020 15:04:31

FDA-CBER-2022-1614-1779575

US3472001
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:42:27
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:24:16
User entered empty.	Debora Dunbar (b) (4) (b) (4)	28 Nov 2020 15:04:31

FDA-CBER-2022-1614-1779576

US3472001
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:42:27
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:24:16
User entered empty.	Debora Dunbar (b) (4) (b) (4)	28 Nov 2020 15:04:31

FDA-CBER-2022-1614-1779577

US3472001
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:42:27
Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:24:16
User entered empty.	Debora Dunbar (b) (4) (b) (4)	28 Nov 2020 15:04:31

FDA-CBER-2022-1614-1779578

US3472001
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:42:27
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:24:16
User entered '0'	Debora Dunbar (b) (4) (b) (4)	28 Nov 2020 15:04:31

FDA-CBER-2022-1614-1779579

US3472001
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:42:27
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:24:16
User entered '0'	Debora Dunbar (b) (4) (b) (4)	28 Nov 2020 15:04:31

FDA-CBER-2022-1614-1779580

US3472001
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:42:27
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:24:16
User entered '0'	Debora Dunbar (b) (4) (b) (4)	28 Nov 2020 15:04:31

US3472001
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:42:27
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:24:16
User entered 'Not Related (NOT RELATED)'	Debora Dunbar (b) (4) (b) (4)	28 Nov 2020 15:04:31

FDA-CBER-2022-1614-1779582

US3472001
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:42:27
Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:24:16
User entered 'Not Related (NOT RELATED)'	Debora Dunbar (b) (4) (b) (4)	28 Nov 2020 15:04:31

FDA-CBER-2022-1614-1779583

US3472001
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:42:27
Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:24:16
User entered 'Not Applicable (NOT APPLICABLE)'	Debora Dunbar (b) (4) (b) (4)	28 Nov 2020 15:04:31

FDA-CBER-2022-1614-1779584

US3472001
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:42:27
None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:24:16
User entered '1'	Debora Dunbar (b) (4) (b) (4)	28 Nov 2020 15:04:31

FDA-CBER-2022-1614-1779585

US3472001
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:42:27
Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:24:16
User entered '0'	Debora Dunbar (b) (4) (b) (4)	28 Nov 2020 15:04:31

FDA-CBER-2022-1614-1779586

US3472001
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:42:27
Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:24:16
User entered '0'	Debora Dunbar (b) (4) (b) (4)	28 Nov 2020 15:04:31

FDA-CBER-2022-1614-1779587

US3472001
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:42:27
Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:24:16
User entered 'Fatal (FATAL)'	Debora Dunbar (b) (4) (b) (4)	28 Nov 2020 15:04:31

US3472001
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:42:27
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:24:16
User entered empty.	Debora Dunbar (b) (4) (b) (4)	28 Nov 2020 15:04:31

FDA-CBER-2022-1614-1779589

US3472001
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:42:27
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
User closed query '(MR Query AI#9) PV Query: Please update the event term to primary cause of death, once known, and consider splitting event to outline provisional diagnosis and death. If event remains unknown, please update event term to provisional diagnosis only.--Site responded "we are unable to obtain the death certificate and therefore cannot provide this information". ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	04 Mar 2021 14:30:47
Query '(MR Query AI#9) PV Query: Please update the event term to primary cause of death, once known, and consider splitting event to outline provisional diagnosis and death. If event remains unknown, please update event term to provisional diagnosis only.--Site responded "we are unable to obtain the death certificate and therefore cannot provide this information". ' answered with 'updated event term to provisional diagnosis only. ' (Site from Safety).	(b) (4), (b) (6)	03 Mar 2021 13:55:24
User opened query '(MR Query AI#9) PV Query: Please update the event term to primary cause of death, once known, and consider splitting event to outline provisional diagnosis and death. If event remains unknown, please update event term to provisional diagnosis only.--Site responded "we are unable to obtain the death certificate and therefore cannot provide this information". ' (Site from Safety).	(b) (4), (b) (6)	03 Mar 2021 13:45:05
User closed query 'PV Query: Please send a death certificate, and autopsy results (if performed) with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342.' (Site from Safety).	(b) (4), (b) (6)	24 Feb 2021 15:45:57
User closed query 'PV Query: Please provide the patient's health status in the days surrounding death.' (Site from Safety).	(b) (4), (b) (6)	24 Feb 2021 15:45:54
User closed query 'PV Query: Please provide/confirm the cause of death.' (Site from Safety).	(b) (4), (b) (6)	24 Feb 2021 15:45:50

FDA-CBER-2022-1614-1779590

US3472001
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:42:27
Narrative

Audit	User	Time (GMT)
Query 'PV Query: Please send a death certificate, and autopsy results (if performed) with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342.' answered with 'we are unable to obtain the death certificate and therefore cannot provide this information' (Site from Safety).	(b) (4), (b) (6)	23 Feb 2021 18:01:10
Query 'PV Query: Please provide the patient's health status in the days surrounding death.' answered with 'we are unable to obtain the death certificate and therefore cannot provide this information' (Site from Safety).	(b) (4), (b) (6)	23 Feb 2021 18:01:05
Query 'PV Query: Please provide/confirm the cause of death.' answered with 'we are unable to obtain the death certificate and therefore cannot provide this information' (Site from Safety).	(b) (4), (b) (6)	23 Feb 2021 18:01:01
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:24:16
User closed query 'PV Query: Please provide autopsy results if performed. If not performed, please state so.' (Site from Safety).	(b) (4), (b) (6)	08 Dec 2020 15:24:02
Query 'PV Query: Please provide autopsy results if performed. If not performed, please state so.' answered with 'Family refused autopsy.' (Site from Safety).	Jie Ho (b) (4)	07 Dec 2020 21:42:25
User entered 'PARTICIPANT FOUND DEAD ON BATHROOM FLOOR ON 11/27/20. TIME OF DEATH NOT YET DETERMINED. CAUSE OF DEATH NOT DETERMINED. REQUESTING FAMILY PERMISSION TO CONDUCT LIMITED POST MORTEM EXAM. 12/3 Update: Family refused post mortem exam.' reason for change: Per Query Resolution	Jie Ho (b) (4)	07 Dec 2020 21:41:54
User opened query 'PV Query: Please send a death certificate, and autopsy results (if performed) with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342.' (Site from Safety).	(b) (4), (b) (6)	06 Dec 2020 16:59:15
User opened query 'PV Query: Please provide the patient's health status in the days surrounding death.' (Site from Safety).	(b) (4), (b) (6)	06 Dec 2020 16:58:50

US3472001
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:42:27
Narrative

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide autopsy results if performed. If not performed, please state so.' (Site from Safety).	(b) (4), (b) (6)	06 Dec 2020 16:58:29
User opened query 'PV Query: Please provide/confirm the cause of death.' (Site from Safety).	(b) (4), (b) (6)	06 Dec 2020 16:57:56
User entered 'Participant found dead on bathroom floor on 11/27/20. Time of death not yet determined. Cause of death not determined. Requesting family permission to conduct limited post mortem exam.'	Debora Dunbar (b) (4) (b) (4)	28 Nov 2020 15:04:31

FDA-CBER-2022-1614-1779592

US3472001
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:42:27
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered '1'	System	28 Nov 2020 15:04:31

FDA-CBER-2022-1614-1779593

US3472001
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:42:27
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered '0'	System	28 Nov 2020 15:04:31

FDA-CBER-2022-1614-1779594

US3472001
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 17:42:27
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19

FDA-CBER-2022-1614-1779595

US3472001
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:42:27
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19

FDA-CBER-2022-1614-1779596

US3472001
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:42:27
Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19

FDA-CBER-2022-1614-1779597

US3472001
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:42:27
Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19

FDA-CBER-2022-1614-1779598

US3472001
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:42:27
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19

FDA-CBER-2022-1614-1779599

US3472001
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:42:27
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19

FDA-CBER-2022-1614-1779600

US3472001
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:42:27
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19

FDA-CBER-2022-1614-1779601

US3472001
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:42:27
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19

FDA-CBER-2022-1614-1779602

US3472001
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:42:27
AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19

FDA-CBER-2022-1614-1779603

US3472001
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:42:27
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19

FDA-CBER-2022-1614-1779604

US3472001
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:42:27
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19

FDA-CBER-2022-1614-1779605

US3472001
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:42:27
End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19

FDA-CBER-2022-1614-1779606

US3472001
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:42:27
AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19

FDA-CBER-2022-1614-1779607

US3472001
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:42:27
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19

FDA-CBER-2022-1614-1779608

US3472001
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:42:27
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19

FDA-CBER-2022-1614-1779609

US3472001
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:42:27
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19

FDA-CBER-2022-1614-1779610

US3472001
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:42:27
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19

FDA-CBER-2022-1614-1779611

US3472001
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:42:27
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19

FDA-CBER-2022-1614-1779612

US3472001
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:42:27
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19

FDA-CBER-2022-1614-1779613

US3472001
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:42:27
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19

FDA-CBER-2022-1614-1779614

US3472001
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:42:27
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19

FDA-CBER-2022-1614-1779615

US3472001
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:42:27
Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19

FDA-CBER-2022-1614-1779616

US3472001
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:42:27
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19

FDA-CBER-2022-1614-1779617

US3472001
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:42:27
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19

FDA-CBER-2022-1614-1779618

US3472001
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:42:27
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19

FDA-CBER-2022-1614-1779619

US3472001
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:42:27
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19

FDA-CBER-2022-1614-1779620

US3472001
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:42:27
Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19

FDA-CBER-2022-1614-1779621

US3472001
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:42:27
Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19

FDA-CBER-2022-1614-1779622

US3472001
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:42:27
None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19

FDA-CBER-2022-1614-1779623

US3472001
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:42:27
Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19

FDA-CBER-2022-1614-1779624

US3472001
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:42:27
Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19

FDA-CBER-2022-1614-1779625

US3472001
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:42:27
Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19

FDA-CBER-2022-1614-1779626

US3472001
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:42:27
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19

FDA-CBER-2022-1614-1779627

US3472001
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:42:27
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19

FDA-CBER-2022-1614-1779628

US3472001
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:42:27
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19

FDA-CBER-2022-1614-1779629

US3472001
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:42:27
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19

FDA-CBER-2022-1614-1779630

US3472001
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 17:42:27
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19

FDA-CBER-2022-1614-1779631

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination Summary
Generated On: 09 Jun 2021 17:42:27
Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:25:15
User entered 'Yes (Y)'	Jie Ho (b) (4)	31 Aug 2020 17:57:56

FDA-CBER-2022-1614-1779632

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 17:42:27
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 17:24:54
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN, PRODUCTSYNONYM: ELIQUIS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 18:01:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 18:01:42
Data point term sent to Coder	System	31 Aug 2020 18:00:13
User entered 'Eliquis'	Jie Ho (b) (4)	31 Aug 2020 17:59:25

FDA-CBER-2022-1614-1779633

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 17:42:27
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:24:54
User entered 'Yes (Y)'	Jie Ho (b) (4)	31 Aug 2020 17:59:25

FDA-CBER-2022-1614-1779634

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 17:42:27
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:24:54
User entered 'Prophylaxis for VTE'	Jie Ho (b) (4)	31 Aug 2020 17:59:25

FDA-CBER-2022-1614-1779635

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 17:42:27
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:24:54
User entered '5'	Jie Ho (b) (4)	31 Aug 2020 17:59:25

FDA-CBER-2022-1614-1779636

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 17:42:27
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:24:54
User entered 'mg (mg)'	Jie Ho (b) (4)	31 Aug 2020 17:59:25

FDA-CBER-2022-1614-1779637

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 17:42:27
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:24:54
User entered empty.	Jie Ho (b) (4)	31 Aug 2020 17:59:25

FDA-CBER-2022-1614-1779638

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 17:42:27
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:24:54
User entered 'twice daily (BID)'	Jie Ho (b) (4)	31 Aug 2020 17:59:25

FDA-CBER-2022-1614-1779639

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 17:42:27
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:24:54
User entered empty.	Jie Ho (b) (4)	31 Aug 2020 17:59:25

FDA-CBER-2022-1614-1779640

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 17:42:27
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:24:54
User entered 'Oral (ORAL)'	Jie Ho (b) (4)	31 Aug 2020 17:59:25

FDA-CBER-2022-1614-1779641

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 17:42:27
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:24:54
User entered empty.	Jie Ho (b) (4)	31 Aug 2020 17:59:25

FDA-CBER-2022-1614-1779642

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 17:42:27
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:24:54
User entered 'un UNK 2016'	Jie Ho (b) (4)	31 Aug 2020 17:59:25

FDA-CBER-2022-1614-1779643

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 17:42:27
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:24:54
User entered '0'	Jie Ho (b) (4)	31 Aug 2020 17:59:25

FDA-CBER-2022-1614-1779644

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 17:42:27
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:24:54
User entered 'Yes (Y)'	Jie Ho (b) (4)	31 Aug 2020 17:59:25

FDA-CBER-2022-1614-1779645

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 17:42:27
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:24:54
User entered empty.	Jie Ho (b) (4)	31 Aug 2020 17:59:25

FDA-CBER-2022-1614-1779646

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 17:42:27
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:24:54
User entered 'No (N)'	Jie Ho (b) (4)	31 Aug 2020 17:59:25

FDA-CBER-2022-1614-1779647

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 17:42:27
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered '2'	System	31 Aug 2020 17:59:25

FDA-CBER-2022-1614-1779648

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 17:42:27
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered '1'	System	31 Aug 2020 17:59:25

FDA-CBER-2022-1614-1779649

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 17:42:27
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered '804 (804)'	System	31 Aug 2020 17:59:25

FDA-CBER-2022-1614-1779650

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 17:42:27
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 17:24:54
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 18:01:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 18:01:43
Data point term sent to Coder	System	31 Aug 2020 18:01:16
User entered 'Atorvastatin'	Jie Ho (b) (4)	31 Aug 2020 18:00:23

FDA-CBER-2022-1614-1779651

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 17:42:27
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:24:54
User entered 'No (N)'	Jie Ho (b) (4)	31 Aug 2020 18:00:23

FDA-CBER-2022-1614-1779652

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 17:42:27
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:24:54
User entered 'Hyperlipidemia'	Jie Ho (b) (4)	31 Aug 2020 18:00:23

FDA-CBER-2022-1614-1779653

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 17:42:27
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:24:54
User entered '20'	Jie Ho (b) (4)	31 Aug 2020 18:00:23

FDA-CBER-2022-1614-1779654

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 17:42:27
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:24:54
User entered 'mg (mg)'	Jie Ho (b) (4)	31 Aug 2020 18:00:23

FDA-CBER-2022-1614-1779655

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 17:42:27
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:24:54
User entered empty.	Jie Ho (b) (4)	31 Aug 2020 18:00:23

FDA-CBER-2022-1614-1779656

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 17:42:27
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:24:54
User entered 'once daily (QD)'	Jie Ho (b) (4)	31 Aug 2020 18:00:23

FDA-CBER-2022-1614-1779657

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 17:42:27
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:24:54
User entered empty.	Jie Ho (b) (4)	31 Aug 2020 18:00:23

FDA-CBER-2022-1614-1779658

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 17:42:27
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:24:54
User entered 'Oral (ORAL)'	Jie Ho (b) (4)	31 Aug 2020 18:00:23

FDA-CBER-2022-1614-1779659

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 17:42:27
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:24:54
User entered empty.	Jie Ho (b) (4)	31 Aug 2020 18:00:23

FDA-CBER-2022-1614-1779660

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 17:42:27
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:24:54
User entered 'un UNK 2010'	Jie Ho (b) (4)	31 Aug 2020 18:00:23

FDA-CBER-2022-1614-1779661

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 17:42:27
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:24:54
User entered '0'	Jie Ho (b) (4)	31 Aug 2020 18:00:23

FDA-CBER-2022-1614-1779662

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 17:42:27
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:24:54
User entered 'Yes (Y)'	Jie Ho (b) (4)	31 Aug 2020 18:00:23

FDA-CBER-2022-1614-1779663

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 17:42:27
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:24:54
User entered empty.	Jie Ho (b) (4)	31 Aug 2020 18:00:23

FDA-CBER-2022-1614-1779664

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 17:42:27
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:24:54
User entered 'No (N)'	Jie Ho (b) (4)	31 Aug 2020 18:00:23

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 17:42:27
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered '1'	System	31 Aug 2020 18:00:23

FDA-CBER-2022-1614-1779666

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 17:42:27
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered '1'	System	31 Aug 2020 18:00:23

FDA-CBER-2022-1614-1779667

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 17:42:27
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered '804 (804)'	System	31 Aug 2020 18:00:23

FDA-CBER-2022-1614-1779668

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 17:42:27
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, PRODUCT: VITAMIN B NOS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 11:57:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Sep 2020 11:57:50
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 17:24:54
Data point term sent to Coder	System	31 Aug 2020 18:01:17
User entered 'Vitamin B Supplement'	Jie Ho (b) (4)	31 Aug 2020 18:01:02

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 17:42:27
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:24:54
User entered 'Yes (Y)' reason for change: Data Entry Error	Jie Ho (b) (4)	31 Aug 2020 18:02:37
User entered 'No (N)'	Jie Ho (b) (4)	31 Aug 2020 18:01:02

FDA-CBER-2022-1614-1779670

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 17:42:27
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:24:54
User entered 'Health Promotion'	Jie Ho (b) (4)	31 Aug 2020 18:01:02

FDA-CBER-2022-1614-1779671

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 17:42:27
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:24:54
User entered '1'	Jie Ho (b) (4)	31 Aug 2020 18:01:02

FDA-CBER-2022-1614-1779672

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 17:42:27
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:24:54
User entered 'tablet (TABLET)'	Jie Ho (b) (4)	31 Aug 2020 18:01:02

FDA-CBER-2022-1614-1779673

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 17:42:27
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:24:54
User entered empty.	Jie Ho (b) (4)	31 Aug 2020 18:01:02

FDA-CBER-2022-1614-1779674

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 17:42:27
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:24:54
User entered 'once daily (QD)'	Jie Ho (b) (4)	31 Aug 2020 18:01:02

FDA-CBER-2022-1614-1779675

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 17:42:27
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:24:54
User entered empty.	Jie Ho (b) (4)	31 Aug 2020 18:01:02

FDA-CBER-2022-1614-1779676

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 17:42:27
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:24:54
User entered 'Oral (ORAL)'	Jie Ho (b) (4)	31 Aug 2020 18:01:02

FDA-CBER-2022-1614-1779677

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 17:42:27
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:24:54
User entered empty.	Jie Ho (b) (4)	31 Aug 2020 18:01:02

FDA-CBER-2022-1614-1779678

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 17:42:27
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:24:54
User entered 'un Sep 2019'	Jie Ho (b) (4)	31 Aug 2020 18:01:02

FDA-CBER-2022-1614-1779679

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 17:42:27
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:24:54
User entered '0'	Jie Ho (b) (4)	31 Aug 2020 18:01:02

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 17:42:27
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:24:54
User entered 'Yes (Y)'	Jie Ho (b) (4)	31 Aug 2020 18:01:02

FDA-CBER-2022-1614-1779681

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 17:42:27
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:24:54
User entered empty.	Jie Ho (b) (4)	31 Aug 2020 18:01:02

FDA-CBER-2022-1614-1779682

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 17:42:27
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:24:54
User entered 'No (N)'	Jie Ho (b) (4)	31 Aug 2020 18:01:02

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 17:42:27
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered '1'	System	31 Aug 2020 18:01:02

FDA-CBER-2022-1614-1779684

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 17:42:27
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered '1'	System	31 Aug 2020 18:01:02

FDA-CBER-2022-1614-1779685

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 17:42:27
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered '804 (804)'	System	31 Aug 2020 18:01:02

FDA-CBER-2022-1614-1779686

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 17:42:27
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 17:24:54
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: CONTACT LAXATIVES, PRODUCT: BISACODYL, PRODUCTSYNONYM: DULCOLAX [BISACODYL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 07:14:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 07:14:43
Data point term sent to Coder	System	31 Aug 2020 18:02:24
User entered 'Ducolax'	Jie Ho (b) (4)	31 Aug 2020 18:02:15

FDA-CBER-2022-1614-1779687

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 17:42:27
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:24:54
User entered 'No (N)'	Jie Ho (b) (4)	31 Aug 2020 18:02:15

FDA-CBER-2022-1614-1779688

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 17:42:27
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 07:47:05
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'MH updated, thank you.' (Site from DM).	Jie Ho (b) (4)	12 Oct 2020 20:54:38
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 11:10:35
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 17:24:54
User entered 'Constipation'	Jie Ho (b) (4)	31 Aug 2020 18:02:15

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 17:42:27
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:24:54
User entered '5'	Jie Ho (b) (4)	31 Aug 2020 18:02:15

FDA-CBER-2022-1614-1779690

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 17:42:27
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:24:54
User entered 'mg (mg)'	Jie Ho (b) (4)	31 Aug 2020 18:02:15

FDA-CBER-2022-1614-1779691

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 17:42:27
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:24:54
User entered empty.	Jie Ho (b) (4)	31 Aug 2020 18:02:15

FDA-CBER-2022-1614-1779692

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 17:42:27
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:24:54
User entered 'as needed (PRN)'	Jie Ho (b) (4)	31 Aug 2020 18:02:15

FDA-CBER-2022-1614-1779693

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 17:42:27
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:24:54
User entered empty.	Jie Ho (b) (4)	31 Aug 2020 18:02:15

FDA-CBER-2022-1614-1779694

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 17:42:27
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:24:54
User entered 'Oral (ORAL)'	Jie Ho (b) (4)	31 Aug 2020 18:02:15

FDA-CBER-2022-1614-1779695

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 17:42:27
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:24:54
User entered empty.	Jie Ho (b) (4)	31 Aug 2020 18:02:15

FDA-CBER-2022-1614-1779696

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 17:42:27
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:24:54
User entered 'un UNK 2010'	Jie Ho (b) (4)	31 Aug 2020 18:02:15

FDA-CBER-2022-1614-1779697

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 17:42:27
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:24:54
User entered '0'	Jie Ho (b) (4)	31 Aug 2020 18:02:15

FDA-CBER-2022-1614-1779698

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 17:42:27
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:24:54
User entered 'Yes (Y)'	Jie Ho (b) (4)	31 Aug 2020 18:02:15

FDA-CBER-2022-1614-1779699

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 17:42:27
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:24:54
User entered empty.	Jie Ho (b) (4)	31 Aug 2020 18:02:15

FDA-CBER-2022-1614-1779700

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 17:42:27
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:24:54
User entered 'No (N)'	Jie Ho (b) (4)	31 Aug 2020 18:02:15

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 17:42:27
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered empty.	System	31 Aug 2020 18:02:15

FDA-CBER-2022-1614-1779702

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 17:42:27
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered empty.	System	31 Aug 2020 18:02:15

FDA-CBER-2022-1614-1779703

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 17:42:27
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered empty.	System	31 Aug 2020 18:02:15

FDA-CBER-2022-1614-1779704

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 17:42:27
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:24:54
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: SOFTENERS, EMOLLIENTS, PRODUCT: DOCUSATE SODIUM, PRODUCTSYNONYM: COLACE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 18:05:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 18:05:41
Data point term sent to Coder	System	31 Aug 2020 18:04:29
User entered 'Colace'	Jie Ho (b) (4)	31 Aug 2020 18:03:28

FDA-CBER-2022-1614-1779705

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 17:42:27
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:24:54
User entered 'No (N)'	Jie Ho (b) (4)	31 Aug 2020 18:03:28

FDA-CBER-2022-1614-1779706

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 17:42:27
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 07:47:21
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'MH updated, thank you.' (Site from DM).	Jie Ho (b) (4)	12 Oct 2020 20:54:48
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 11:10:48
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 17:24:54
User entered 'Constipation'	Jie Ho (b) (4)	31 Aug 2020 18:03:28

FDA-CBER-2022-1614-1779707

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 17:42:27
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:24:54
User entered '100'	Jie Ho (b) (4)	31 Aug 2020 18:03:28

FDA-CBER-2022-1614-1779708

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 17:42:27
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:24:54
User entered 'mg (mg)'	Jie Ho (b) (4)	31 Aug 2020 18:03:28

FDA-CBER-2022-1614-1779709

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 17:42:27
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:24:54
User entered empty.	Jie Ho (b) (4)	31 Aug 2020 18:03:28

FDA-CBER-2022-1614-1779710

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 17:42:27
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:24:54
User entered 'as needed (PRN)'	Jie Ho (b) (4)	31 Aug 2020 18:03:28

FDA-CBER-2022-1614-1779711

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 17:42:27
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:24:54
User entered empty.	Jie Ho (b) (4)	31 Aug 2020 18:03:28

FDA-CBER-2022-1614-1779712

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 17:42:27
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:24:54
User entered 'Oral (ORAL)'	Jie Ho (b) (4)	31 Aug 2020 18:03:28

FDA-CBER-2022-1614-1779713

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 17:42:27
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:24:54
User entered empty.	Jie Ho (b) (4)	31 Aug 2020 18:03:28

FDA-CBER-2022-1614-1779714

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 17:42:27
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:24:54
User entered 'un UNK 2010'	Jie Ho (b) (4)	31 Aug 2020 18:03:28

FDA-CBER-2022-1614-1779715

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 17:42:27
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:24:54
User entered '0'	Jie Ho (b) (4)	31 Aug 2020 18:03:28

FDA-CBER-2022-1614-1779716

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 17:42:27
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:24:54
User entered 'Yes (Y)'	Jie Ho (b) (4)	31 Aug 2020 18:03:28

FDA-CBER-2022-1614-1779717

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 17:42:27
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:24:54
User entered empty.	Jie Ho (b) (4)	31 Aug 2020 18:03:28

FDA-CBER-2022-1614-1779718

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 17:42:27
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:24:54
User entered 'No (N)'	Jie Ho (b) (4)	31 Aug 2020 18:03:28

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 17:42:27
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered empty.	System	31 Aug 2020 18:03:28

FDA-CBER-2022-1614-1779720

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 17:42:27
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered empty.	System	31 Aug 2020 18:03:28

FDA-CBER-2022-1614-1779721

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 17:42:27
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered empty.	System	31 Aug 2020 18:03:28

FDA-CBER-2022-1614-1779722

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 17:42:27
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 17:24:54
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), COMBINATIONS, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS) AND DIURETICS, PRODUCT: HYDROCHLOROTHIAZIDE;LOSARTAN POTASSIUM, PRODUCTSYNONYM: LOSARTAN/HCTZ - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 10:26:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 10:26:50
Data point term sent to Coder	System	31 Aug 2020 18:06:37
User entered 'Losartin-HCTZ'	Jie Ho (b) (4)	31 Aug 2020 18:06:19

FDA-CBER-2022-1614-1779723

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 17:42:27
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:24:54
User entered 'No (N)'	Jie Ho (b) (4)	31 Aug 2020 18:06:19

FDA-CBER-2022-1614-1779724

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 17:42:27
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:24:54
User entered 'Hypertension'	Jie Ho (b) (4)	31 Aug 2020 18:06:19

FDA-CBER-2022-1614-1779725

US3472001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:42:27

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
User closed query 'Per DM CLR: Please use slash (/) as a separator for combination medication instead of dash (-). Update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Oct 2020 07:47:29
Query 'Per DM CLR: Please use slash (/) as a separator for combination medication instead of dash (-). Update as appropriate.' answered with 'Updated, thank you.' (Site from DM).	Jie Ho (b) (4)	12 Oct 2020 12:46:31
DataPoint Un-verified.	Jie Ho (b) (4)	12 Oct 2020 12:46:13
User entered '100/25' reason for change: Per Query Resolution	Jie Ho (b) (4)	12 Oct 2020 12:46:13
User opened query 'Per DM CLR: Please use slash (/) as a separator for combination medication instead of dash (-). Update as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 11:11:23
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 17:24:54
User entered '100-25'	Jie Ho (b) (4)	31 Aug 2020 18:06:19

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 17:42:27
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:24:54
User entered 'mg (mg)'	Jie Ho (b) (4)	31 Aug 2020 18:06:19

FDA-CBER-2022-1614-1779727

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 17:42:27
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:24:54
User entered empty.	Jie Ho (b) (4)	31 Aug 2020 18:06:19

FDA-CBER-2022-1614-1779728

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 17:42:27
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:24:54
User entered 'once daily (QD)'	Jie Ho (b) (4)	31 Aug 2020 18:06:19

FDA-CBER-2022-1614-1779729

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 17:42:27
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:24:54
User entered empty.	Jie Ho (b) (4)	31 Aug 2020 18:06:19

FDA-CBER-2022-1614-1779730

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 17:42:27
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:24:54
User entered 'Oral (ORAL)'	Jie Ho (b) (4)	31 Aug 2020 18:06:19

FDA-CBER-2022-1614-1779731

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 17:42:27
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:24:54
User entered empty.	Jie Ho (b) (4)	31 Aug 2020 18:06:19

FDA-CBER-2022-1614-1779732

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 17:42:27
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:24:54
User entered 'un UNK 2005'	Jie Ho (b) (4)	31 Aug 2020 18:06:19

FDA-CBER-2022-1614-1779733

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 17:42:27
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:24:54
User entered '0'	Jie Ho (b) (4)	31 Aug 2020 18:06:19

FDA-CBER-2022-1614-1779734

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 17:42:27
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:24:54
User entered 'Yes (Y)'	Jie Ho (b) (4)	31 Aug 2020 18:06:19

FDA-CBER-2022-1614-1779735

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 17:42:27
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:24:54
User entered empty.	Jie Ho (b) (4)	31 Aug 2020 18:06:19

FDA-CBER-2022-1614-1779736

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 17:42:27
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:24:54
User entered 'No (N)'	Jie Ho (b) (4)	31 Aug 2020 18:06:19

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 17:42:27
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered '1'	System	31 Aug 2020 18:06:19

FDA-CBER-2022-1614-1779738

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 17:42:27
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered '1'	System	31 Aug 2020 18:06:19

FDA-CBER-2022-1614-1779739

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 17:42:27
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered '804 (804)'	System	31 Aug 2020 18:06:19

FDA-CBER-2022-1614-1779740

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 17:42:27
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4), (b) (6)	03 Sep 2020 17:24:54
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 18:08:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 18:08:36
Data point term sent to Coder	System	31 Aug 2020 18:07:38
User entered 'Metropolol'	Jie Ho (b) (4)	31 Aug 2020 18:06:51

FDA-CBER-2022-1614-1779741

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 17:42:27
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:24:54
User entered 'No (N)'	Jie Ho (b) (4)	31 Aug 2020 18:06:51

FDA-CBER-2022-1614-1779742

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 17:42:27
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:24:54
User entered 'Hypertension'	Jie Ho (b) (4)	31 Aug 2020 18:06:51

FDA-CBER-2022-1614-1779743

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 17:42:27
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:24:54
User entered '25'	Jie Ho (b) (4)	31 Aug 2020 18:06:51

FDA-CBER-2022-1614-1779744

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 17:42:27
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:24:54
User entered 'mg (mg)'	Jie Ho (b) (4)	31 Aug 2020 18:06:51

FDA-CBER-2022-1614-1779745

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 17:42:27
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:24:54
User entered empty.	Jie Ho (b) (4)	31 Aug 2020 18:06:51

FDA-CBER-2022-1614-1779746

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 17:42:27
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:24:54
User entered 'once daily (QD)'	Jie Ho (b) (4)	31 Aug 2020 18:06:51

FDA-CBER-2022-1614-1779747

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 17:42:27
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:24:54
User entered empty.	Jie Ho (b) (4)	31 Aug 2020 18:06:51

FDA-CBER-2022-1614-1779748

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 17:42:27
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:24:54
User entered 'Oral (ORAL)'	Jie Ho (b) (4)	31 Aug 2020 18:06:51

FDA-CBER-2022-1614-1779749

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 17:42:27
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:24:54
User entered empty.	Jie Ho (b) (4)	31 Aug 2020 18:06:51

FDA-CBER-2022-1614-1779750

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 17:42:27
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:24:54
User entered 'un UNK 2005'	Jie Ho (b) (4)	31 Aug 2020 18:06:51

FDA-CBER-2022-1614-1779751

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 17:42:27
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:24:54
User entered '0'	Jie Ho (b) (4)	31 Aug 2020 18:06:51

FDA-CBER-2022-1614-1779752

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 17:42:27
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:24:54
User entered 'Yes (Y)'	Jie Ho (b) (4)	31 Aug 2020 18:06:51

FDA-CBER-2022-1614-1779753

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 17:42:27
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:24:54
User entered empty.	Jie Ho (b) (4)	31 Aug 2020 18:06:51

FDA-CBER-2022-1614-1779754

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 17:42:27
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 17:24:54
User entered 'No (N)'	Jie Ho (b) (4)	31 Aug 2020 18:06:51

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 17:42:27
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered '1'	System	31 Aug 2020 18:06:51

FDA-CBER-2022-1614-1779756

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 17:42:27
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered '1'	System	31 Aug 2020 18:06:51

FDA-CBER-2022-1614-1779757

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 17:42:27
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered '804 (804)'	System	31 Aug 2020 18:06:51

FDA-CBER-2022-1614-1779758

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 17:42:27
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
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)	21 Sep 2020 18:56:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 18:56:52
Data point term sent to Coder	System	21 Sep 2020 18:55:49
User entered 'Influenza vaccine'	(b) (4), (b) (6)	21 Sep 2020 18:55:12

FDA-CBER-2022-1614-1779759

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 17:42:27
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 18:55:12

FDA-CBER-2022-1614-1779760

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 17:42:27
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
User entered 'prophylaxis'	(b) (4), (b) (6)	21 Sep 2020 18:55:12

FDA-CBER-2022-1614-1779761

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 17:42:27
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
User entered '0.7'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 18:55:12

FDA-CBER-2022-1614-1779762

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 17:42:27
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
User entered 'mL (mL)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 18:55:12

FDA-CBER-2022-1614-1779763

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 17:42:27
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 18:55:12

FDA-CBER-2022-1614-1779764

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 17:42:27
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 18:55:12

FDA-CBER-2022-1614-1779765

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 17:42:27
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 18:55:12

FDA-CBER-2022-1614-1779766

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 17:42:27
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 18:55:12

FDA-CBER-2022-1614-1779767

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 17:42:27
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 18:55:12

FDA-CBER-2022-1614-1779768

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 17:42:27
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
User entered '15 Sep 2020'	(b) (4), (b) (6)	21 Sep 2020 18:55:12

FDA-CBER-2022-1614-1779769

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 17:42:27
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 18:55:12

FDA-CBER-2022-1614-1779770

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 17:42:27
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 18:55:12

FDA-CBER-2022-1614-1779771

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 17:42:27
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
User entered '15 Sep 2020'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 18:55:12

FDA-CBER-2022-1614-1779772

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 17:42:27
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 18:55:12

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 17:42:27
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered empty.	System	21 Sep 2020 18:55:12

FDA-CBER-2022-1614-1779774

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 17:42:27
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered empty.	System	21 Sep 2020 18:55:12

FDA-CBER-2022-1614-1779775

US3472001
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 17:42:27
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered empty.	System	21 Sep 2020 18:55:12

FDA-CBER-2022-1614-1779776

US3472001
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures Summary
Generated On: 09 Jun 2021 17:42:27
Were any concomitant procedures performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:19:26

FDA-CBER-2022-1614-1779777

US3472001
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 09 Jun 2021 17:42:27
Date of study discontinuation/completion *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:05:09
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
User entered '27 Nov 2020'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 19:18:12

FDA-CBER-2022-1614-1779778

US3472001
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 09 Jun 2021 17:42:27
Reason for discontinuation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:05:09
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
User entered 'Death (DEATH)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 19:18:12

FDA-CBER-2022-1614-1779779

US3472001

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:42:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:05:09
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
User entered empty.	(b) (4), (b) (6)	15 Mar 2021 19:18:12

US3472001
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 09 Jun 2021 17:42:27
If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:05:09
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
User entered 'Adverse event (ADVERSE EVENT)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 19:18:12

FDA-CBER-2022-1614-1779781

US3472001
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 09 Jun 2021 17:42:27
If main cause of death is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:05:09
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
User entered empty.	(b) (4), (b) (6)	15 Mar 2021 19:18:12

FDA-CBER-2022-1614-1779782

US3472001
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 09 Jun 2021 17:42:27
Date of death *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:05:09
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
User entered '27 Nov 2020'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 19:18:12

FDA-CBER-2022-1614-1779783

US3472001
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 09 Jun 2021 17:42:27
Was autopsy performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:05:09
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
User entered 'Unknown (UNK)'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 19:18:12

FDA-CBER-2022-1614-1779784

US3472001
Folder: SAE USA-US122-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 17:42:27
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:23:57
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:08:36
User entered 'USA-US122-2020-MRNA-1273-P301000004'	System	30 Nov 2020 16:08:00

US3472001
Folder: SAE USA-US122-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 17:42:27
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:23:57
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:08:36
User entered 'Yes (Y)'	System	30 Nov 2020 16:08:00

FDA-CBER-2022-1614-1779786

US3472001
Folder: SAE USA-US122-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 17:42:27
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:23:57
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:08:36
User entered 'Yes (Y)'	System	30 Nov 2020 16:08:00

FDA-CBER-2022-1614-1779787

US3472001
Folder: SAE USA-US122-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 17:42:27
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:23:57
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:08:36
User entered 'No (N)'	System	30 Nov 2020 16:08:00

FDA-CBER-2022-1614-1779788

US3472001
Folder: SAE USA-US122-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 17:42:27
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:23:57
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:08:36
User entered 'No (N)'	System	30 Nov 2020 16:08:00

FDA-CBER-2022-1614-1779789

US3472001
Folder: SAE USA-US122-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 17:42:27
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:23:57
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:08:36
User entered 'No (N)'	System	30 Nov 2020 16:08:00

US3472001
Folder: SAE USA-US122-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 17:42:27
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:23:57
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:08:36
User entered 'No (N)'	System	30 Nov 2020 16:08:00

US3472001
Folder: SAE USA-US122-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 17:42:27
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:23:57
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:08:36
User entered 'No (N)'	System	30 Nov 2020 16:08:00

FDA-CBER-2022-1614-1779792

US3472001
Folder: SAE USA-US122-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 17:42:27
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 14:33:39
DataPoint Un-verified.	System	04 Mar 2021 14:33:02
User entered 'Ian'	System	04 Mar 2021 14:33:02
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:23:57
Un-reviewed for Safety.	System	08 Dec 2020 15:25:39
User entered empty.	System	08 Dec 2020 15:25:39
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:25
User entered 'Ian'	Jie Ho (b) (4)	30 Nov 2020 19:35:23

US3472001
Folder: SAE USA-US122-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 17:42:27
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 14:33:39
DataPoint Un-verified.	System	04 Mar 2021 14:33:02
User entered 'Frank'	System	04 Mar 2021 14:33:02
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:23:57
Un-reviewed for Safety.	System	08 Dec 2020 15:25:39
User entered empty.	System	08 Dec 2020 15:25:39
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:25
User entered 'Frank'	Jie Ho (b) (4)	30 Nov 2020 19:35:23

US3472001
Folder: SAE USA-US122-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 17:42:27
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 14:33:39
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:23:57
Un-reviewed for Safety.	System	08 Dec 2020 15:25:39
User entered empty.	System	08 Dec 2020 15:25:39
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:25
User entered '3535 Market Street'	Jie Ho (b) (4)	30 Nov 2020 19:35:23

FDA-CBER-2022-1614-1779795

US3472001
Folder: SAE USA-US122-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 17:42:27
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 14:33:39
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:23:57
Un-reviewed for Safety.	System	08 Dec 2020 15:25:39
User entered empty.	System	08 Dec 2020 15:25:39
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:25
User entered 'Philadelphia'	Jie Ho (b) (4)	30 Nov 2020 19:35:23

US3472001
Folder: SAE USA-US122-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 17:42:27
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 14:33:39
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:23:57
Un-reviewed for Safety.	System	08 Dec 2020 15:25:39
User entered empty.	System	08 Dec 2020 15:25:39
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:25
User entered 'Pennsylvania'	Jie Ho (b) (4)	30 Nov 2020 19:35:23

US3472001
Folder: SAE USA-US122-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 17:42:27
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 14:33:39
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:23:57
Un-reviewed for Safety.	System	08 Dec 2020 15:25:39
User entered empty.	System	08 Dec 2020 15:25:39
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:25
User entered '19104'	Jie Ho (b) (4)	30 Nov 2020 19:35:23

US3472001
Folder: SAE USA-US122-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 17:42:27
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:23:57
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:25
User entered 'US'	System	30 Nov 2020 16:08:43

FDA-CBER-2022-1614-1779799

US3472001
Folder: SAE USA-US122-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 17:42:27
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered '3'	System	04 Mar 2021 14:33:02
User entered '2'	System	08 Dec 2020 15:25:39
User entered '1'	System	30 Nov 2020 16:08:43

US3472001
Folder: SAE USA-US122-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 17:42:27
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:23:57
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:08:36
User entered 'USA-US122-2020-MRNA-1273-P301000004'	System	30 Nov 2020 16:08:00

FDA-CBER-2022-1614-1779801

US3472001
Folder: SAE USA-US122-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 17:42:27
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:23:57
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:08:36
User entered 'Yes (Y)'	System	30 Nov 2020 16:08:00

FDA-CBER-2022-1614-1779802

US3472001
Folder: SAE USA-US122-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 17:42:27
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:23:57
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:08:36
User entered 'Yes (Y)'	System	30 Nov 2020 16:08:00

US3472001
Folder: SAE USA-US122-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 17:42:27
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:23:57
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:08:36
User entered 'No (N)'	System	30 Nov 2020 16:08:00

FDA-CBER-2022-1614-1779804

US3472001
Folder: SAE USA-US122-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 17:42:27
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:23:57
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:08:36
User entered 'No (N)'	System	30 Nov 2020 16:08:00

US3472001
Folder: SAE USA-US122-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 17:42:27
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:23:57
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:08:36
User entered 'No (N)'	System	30 Nov 2020 16:08:00

FDA-CBER-2022-1614-1779806

US3472001
Folder: SAE USA-US122-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 17:42:27
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:23:57
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:08:36
User entered 'No (N)'	System	30 Nov 2020 16:08:00

US3472001
Folder: SAE USA-US122-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 17:42:27
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:23:57
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:08:36
User entered 'No (N)'	System	30 Nov 2020 16:08:00

FDA-CBER-2022-1614-1779808

US3472001
Folder: SAE USA-US122-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 17:42:27
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 14:33:39
DataPoint Un-verified.	System	04 Mar 2021 14:33:02
User entered 'Ian'	System	04 Mar 2021 14:33:02
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:23:57
Un-reviewed for Safety.	System	08 Dec 2020 15:25:39
User entered empty.	System	08 Dec 2020 15:25:39
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:25
User entered 'Ian'	Jie Ho (b) (4)	30 Nov 2020 19:35:23

US3472001
Folder: SAE USA-US122-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 17:42:27
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 14:33:39
DataPoint Un-verified.	System	04 Mar 2021 14:33:02
User entered 'Frank'	System	04 Mar 2021 14:33:02
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:23:57
Un-reviewed for Safety.	System	08 Dec 2020 15:25:39
User entered empty.	System	08 Dec 2020 15:25:39
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:25
User entered 'Frank'	Jie Ho (b) (4)	30 Nov 2020 19:35:23

US3472001
Folder: SAE USA-US122-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 17:42:27
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 14:33:39
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:23:57
Un-reviewed for Safety.	System	08 Dec 2020 15:25:39
User entered empty.	System	08 Dec 2020 15:25:39
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:25
User entered '3535 Market Street'	Jie Ho (b) (4)	30 Nov 2020 19:35:23

US3472001
Folder: SAE USA-US122-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 17:42:27
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 14:33:39
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:23:57
Un-reviewed for Safety.	System	08 Dec 2020 15:25:39
User entered empty.	System	08 Dec 2020 15:25:39
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:25
User entered 'Philadelphia'	Jie Ho (b) (4)	30 Nov 2020 19:35:23

US3472001
Folder: SAE USA-US122-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 17:42:27
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 14:33:39
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:23:57
Un-reviewed for Safety.	System	08 Dec 2020 15:25:39
User entered empty.	System	08 Dec 2020 15:25:39
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:25
User entered 'Pennsylvania'	Jie Ho (b) (4)	30 Nov 2020 19:35:23

US3472001
Folder: SAE USA-US122-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 17:42:27
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 14:33:39
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:23:57
Un-reviewed for Safety.	System	08 Dec 2020 15:25:39
User entered empty.	System	08 Dec 2020 15:25:39
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:25
User entered '19104'	Jie Ho (b) (4)	30 Nov 2020 19:35:23

FDA-CBER-2022-1614-1779814

US3472001
Folder: SAE USA-US122-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 17:42:27
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:23:57
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:25
User entered 'US'	System	30 Nov 2020 16:08:43

US3472001
Folder: SAE USA-US122-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 17:42:27
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered '3'	System	04 Mar 2021 14:33:02
User entered '2'	System	08 Dec 2020 15:25:39
User entered '1'	System	30 Nov 2020 16:08:43

FDA-CBER-2022-1614-1779816

US3472001
Folder: SAE USA-US122-2020-MRNA-1273-P301000004
Form: Safety Report Form (1)
Generated On: 09 Jun 2021 17:42:27
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:23:57
User entered '30/Nov/2020 16:08'	System	30 Nov 2020 16:08:43

FDA-CBER-2022-1614-1779817

US3472001

Folder: SAE USA-US122-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:42:27

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)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:23:57
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:25
User entered '1'	(b) (4), (b) (6)	30 Nov 2020 16:08:43

US3472001
Folder: SAE USA-US122-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 17:42:27
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:23:57
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:08:36
User entered 'USA-US122-2020-MRNA-1273-P301000004'	System	30 Nov 2020 16:08:00

FDA-CBER-2022-1614-1779819

US3472001
Folder: SAE USA-US122-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 17:42:27
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:23:57
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:08:36
User entered 'Yes (Y)'	System	30 Nov 2020 16:08:00

US3472001
Folder: SAE USA-US122-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 17:42:27
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:23:57
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:08:36
User entered 'Yes (Y)'	System	30 Nov 2020 16:08:00

FDA-CBER-2022-1614-1779821

US3472001
Folder: SAE USA-US122-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 17:42:27
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:23:57
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:08:36
User entered 'No (N)'	System	30 Nov 2020 16:08:00

US3472001
Folder: SAE USA-US122-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 17:42:27
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:23:57
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:08:36
User entered 'No (N)'	System	30 Nov 2020 16:08:00

FDA-CBER-2022-1614-1779823

US3472001
Folder: SAE USA-US122-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 17:42:27
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:23:57
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:08:36
User entered 'No (N)'	System	30 Nov 2020 16:08:00

FDA-CBER-2022-1614-1779824

US3472001
Folder: SAE USA-US122-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 17:42:27
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:23:57
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:08:36
User entered 'No (N)'	System	30 Nov 2020 16:08:00

US3472001
Folder: SAE USA-US122-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 17:42:27
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:23:57
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:08:36
User entered 'No (N)'	System	30 Nov 2020 16:08:00

FDA-CBER-2022-1614-1779826

US3472001
Folder: SAE USA-US122-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 17:42:27
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 14:33:39
DataPoint Un-verified.	System	04 Mar 2021 14:33:02
User entered 'Ian'	System	04 Mar 2021 14:33:02
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:23:57
Un-reviewed for Safety.	System	08 Dec 2020 15:25:39
User entered empty.	System	08 Dec 2020 15:25:39
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:25
User entered 'Ian'	Jie Ho (b) (4)	30 Nov 2020 19:35:23

US3472001
Folder: SAE USA-US122-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 17:42:27
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 14:33:39
DataPoint Un-verified.	System	04 Mar 2021 14:33:02
User entered 'Frank'	System	04 Mar 2021 14:33:02
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:23:57
Un-reviewed for Safety.	System	08 Dec 2020 15:25:39
User entered empty.	System	08 Dec 2020 15:25:39
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:25
User entered 'Frank'	Jie Ho (b) (4)	30 Nov 2020 19:35:23

US3472001
Folder: SAE USA-US122-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 17:42:27
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 14:33:39
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:23:57
Un-reviewed for Safety.	System	08 Dec 2020 15:25:39
User entered empty.	System	08 Dec 2020 15:25:39
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:25
User entered '3535 Market Street'	Jie Ho (b) (4)	30 Nov 2020 19:35:23

FDA-CBER-2022-1614-1779829

US3472001
Folder: SAE USA-US122-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 17:42:27
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 14:33:39
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:23:57
Un-reviewed for Safety.	System	08 Dec 2020 15:25:39
User entered empty.	System	08 Dec 2020 15:25:39
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:25
User entered 'Philadelphia'	Jie Ho (b) (4)	30 Nov 2020 19:35:23

US3472001
Folder: SAE USA-US122-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 17:42:27
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 14:33:39
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:23:57
Un-reviewed for Safety.	System	08 Dec 2020 15:25:39
User entered empty.	System	08 Dec 2020 15:25:39
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:25
User entered 'Pennsylvania'	Jie Ho (b) (4)	30 Nov 2020 19:35:23

US3472001
Folder: SAE USA-US122-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 17:42:27
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 14:33:39
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:23:57
Un-reviewed for Safety.	System	08 Dec 2020 15:25:39
User entered empty.	System	08 Dec 2020 15:25:39
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:25
User entered '19104'	Jie Ho (b) (4)	30 Nov 2020 19:35:23

US3472001
Folder: SAE USA-US122-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 17:42:27
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:23:57
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:25
User entered 'US'	System	30 Nov 2020 16:08:43

FDA-CBER-2022-1614-1779833

US3472001
Folder: SAE USA-US122-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 17:42:27
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered '3'	System	04 Mar 2021 14:33:02
User entered '2'	System	08 Dec 2020 15:25:39
User entered '1'	System	30 Nov 2020 16:08:43

FDA-CBER-2022-1614-1779834

US3472001
Folder: SAE USA-US122-2020-MRNA-1273-P301000004
Form: Safety Report Form (2)
Generated On: 09 Jun 2021 17:42:27
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:23:57
User entered '08/Dec/2020 10:25'	System	08 Dec 2020 15:25:39

US3472001

Folder: SAE USA-US122-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:42:27

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)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 14:33:39
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:23:57
User entered '1'	(b) (4), (b) (6)	08 Dec 2020 15:25:39

US3472001
Folder: SAE USA-US122-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 17:42:27
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:23:57
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:08:36
User entered 'USA-US122-2020-MRNA-1273-P301000004'	System	30 Nov 2020 16:08:00

FDA-CBER-2022-1614-1779837

US3472001
Folder: SAE USA-US122-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 17:42:27
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:23:57
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:08:36
User entered 'Yes (Y)'	System	30 Nov 2020 16:08:00

FDA-CBER-2022-1614-1779838

US3472001
Folder: SAE USA-US122-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 17:42:27
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:23:57
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:08:36
User entered 'Yes (Y)'	System	30 Nov 2020 16:08:00

FDA-CBER-2022-1614-1779839

US3472001
Folder: SAE USA-US122-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 17:42:27
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:23:57
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:08:36
User entered 'No (N)'	System	30 Nov 2020 16:08:00

FDA-CBER-2022-1614-1779840

US3472001
Folder: SAE USA-US122-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 17:42:27
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:23:57
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:08:36
User entered 'No (N)'	System	30 Nov 2020 16:08:00

US3472001
Folder: SAE USA-US122-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 17:42:27
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:23:57
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:08:36
User entered 'No (N)'	System	30 Nov 2020 16:08:00

US3472001
Folder: SAE USA-US122-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 17:42:27
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:23:57
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:08:36
User entered 'No (N)'	System	30 Nov 2020 16:08:00

US3472001
Folder: SAE USA-US122-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 17:42:27
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:23:57
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:08:36
User entered 'No (N)'	System	30 Nov 2020 16:08:00

FDA-CBER-2022-1614-1779844

US3472001
Folder: SAE USA-US122-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 17:42:27
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 14:33:39
DataPoint Un-verified.	System	04 Mar 2021 14:33:02
User entered 'Ian'	System	04 Mar 2021 14:33:02
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:23:57
Un-reviewed for Safety.	System	08 Dec 2020 15:25:39
User entered empty.	System	08 Dec 2020 15:25:39
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:25
User entered 'Ian'	Jie Ho (b) (4)	30 Nov 2020 19:35:23

US3472001
Folder: SAE USA-US122-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 17:42:27
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 14:33:39
DataPoint Un-verified.	System	04 Mar 2021 14:33:02
User entered 'Frank'	System	04 Mar 2021 14:33:02
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:23:57
Un-reviewed for Safety.	System	08 Dec 2020 15:25:39
User entered empty.	System	08 Dec 2020 15:25:39
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:25
User entered 'Frank'	Jie Ho (b) (4)	30 Nov 2020 19:35:23

US3472001
Folder: SAE USA-US122-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 17:42:27
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 14:33:39
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:23:57
Un-reviewed for Safety.	System	08 Dec 2020 15:25:39
User entered empty.	System	08 Dec 2020 15:25:39
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:25
User entered '3535 Market Street'	Jie Ho (b) (4)	30 Nov 2020 19:35:23

FDA-CBER-2022-1614-1779847

US3472001
Folder: SAE USA-US122-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 17:42:27
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 14:33:39
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:23:57
Un-reviewed for Safety.	System	08 Dec 2020 15:25:39
User entered empty.	System	08 Dec 2020 15:25:39
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:25
User entered 'Philadelphia'	Jie Ho (b) (4)	30 Nov 2020 19:35:23

FDA-CBER-2022-1614-1779848

US3472001
Folder: SAE USA-US122-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 17:42:27
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 14:33:39
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:23:57
Un-reviewed for Safety.	System	08 Dec 2020 15:25:39
User entered empty.	System	08 Dec 2020 15:25:39
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:25
User entered 'Pennsylvania'	Jie Ho (b) (4)	30 Nov 2020 19:35:23

FDA-CBER-2022-1614-1779849

US3472001
Folder: SAE USA-US122-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 17:42:27
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 14:33:39
DataPoint Verified.	(b) (4), (b) (6)	15 Feb 2021 14:23:57
Un-reviewed for Safety.	System	08 Dec 2020 15:25:39
User entered empty.	System	08 Dec 2020 15:25:39
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:25
User entered '19104'	Jie Ho (b) (4)	30 Nov 2020 19:35:23

FDA-CBER-2022-1614-1779850

US3472001
Folder: SAE USA-US122-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 17:42:27
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4)	29 Mar 2021 15:32:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:23:57
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:25:25
User entered 'US'	System	30 Nov 2020 16:08:43

FDA-CBER-2022-1614-1779851

US3472001
Folder: SAE USA-US122-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 09 Jun 2021 17:42:27
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User entered '3'	System	04 Mar 2021 14:33:02
User entered '2'	System	08 Dec 2020 15:25:39
User entered '1'	System	30 Nov 2020 16:08:43

FDA-CBER-2022-1614-1779852

US3472001
Folder: SAE USA-US122-2020-MRNA-1273-P301000004
Form: Safety Report Form (3)
Generated On: 09 Jun 2021 17:42:27
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
User entered '04/Mar/2021 09:33'	System	04 Mar 2021 14:33:02

FDA-CBER-2022-1614-1779853

US3472001

Folder: SAE USA-US122-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:42:27

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)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:44:19
User signature succeeded.	Ian Frank (b) (4) (b) (4)	29 Mar 2021 15:32:12
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 14:33:39
User entered '1'	(b) (4), (b) (6)	04 Mar 2021 14:33:02