US3862141 (Prod: Baylor College of Medicine)

Generated By: KC Joubran

Generated On: 10 Jun 2021 10:07:51

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US3862141
Form: Participant Creation
Data signed: (b) (4) **02 Apr 2021 14:26:24**
Generated On: 10 Jun 2021 10:07:51

Participant ID	US3862141

mRNA-1273-P301 Completion Guidelines

FDA-CBER-2022-1614-3765919

US3862141
Folder: Screening
Form: Visit Date
Data signed: (b) (4) **13 Feb 2021 00:49:54**
Generated On: 10 Jun 2021 10:07:51

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	08 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	SCRN

FDA-CBER-2022-1614-3765920

US3862141
Folder: Screening
Form: Demographics
Data signed: (b) (4) **13 Feb 2021 00:49:53**
Generated On: 10 Jun 2021 10:07:51

Date of Birth (MMM yyyy)	(b) (6) 1947
Age	72
Age Units	YEARS
Age (Derived)	72
Sex	Female ☐
	Male ■
Ethnicity	Hispanic or Latino ☐
	Not Hispanic or Latino ■
	Not Reported ☐
	Unknown ☐
Race (Check All That Apply)	
White	False
Black	False
Asian	True
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-2022-1614-3765921

US3862141
Folder: Screening
Form: Enrollment
Data signed: (b) (4) **13 Feb 2021 00:49:54**
Generated On: 10 Jun 2021 10:07:51

Date of Informed Consent *(dd MMM yyyy)*	08 SEP 2020
Month and Year of Informed Consent (derived)	SEP 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-2022-1614-3765922

US3862141
Folder: Screening
Form: Inclusion/Exclusion Criteria Summary
Data signed: (b) (4) **13 Feb 2021 00:49:54**
Generated On: 10 Jun 2021 10:07:51

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

FDA-CBER-2022-1614-3765923

US3862141
Folder: Screening
Form: Medical History Summary
Data signed: (b) (4) **13 Feb 2021 00:49:54**
Generated On: 10 Jun 2021 10:07:51

Were any significant conditions reported?	Yes ■ No ☐

FDA-CBER-2022-1614-3765924

US3862141
Folder: Screening
Form: Medical History (1)
Data signed: (b) (4) **13 Feb 2021 00:49:54**
Generated On: 10 Jun 2021 10:07:51

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

FDA-CBER-2022-1614-3765925

US3862141
Folder: Screening
Form: Medical History (2)
Data signed: (b) (4) **13 Feb 2021 00:49:54**
Generated On: 10 Jun 2021 10:07:51

Condition	CONGESTIVE HEART FAILURE
Start date (dd MMM yyyy)	UN UNK 2004
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 2004
Start Year (derived)	2004
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-3765926

US3862141
Folder: Screening
Form: Medical History (3)
Data signed: (b) (4) **13 Feb 2021 00:49:54**
Generated On: 10 Jun 2021 10:07:51

Condition	CORONARY ARTERY DISEASE
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-2022-1614-3765927

US3862141
Folder: Screening
Form: Medical History (4)
Data signed: (b) (4) **13 Feb 2021 00:49:54**
Generated On: 10 Jun 2021 10:07:51

Condition	DIABETES MELLITUS TYPE 2
Start date (dd MMM yyyy)	UN UNK 1990
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 1990
Start Year (derived)	1990
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-3765928

US3862141
Folder: Screening
Form: Medical History (5)
Data signed: (b) (4) **13 Feb 2021 00:49:54**
Generated On: 10 Jun 2021 10:07:51

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2004
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 2004
Start Year (derived)	2004
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-3765929

US3862141
Folder: Screening
Form: Medical History (6)
Data signed: (b) (4) **13 Feb 2021 00:49:54**
Generated On: 10 Jun 2021 10:07:51

Condition	GOUT OF BOTH FEET
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-2022-1614-3765930

US3862141
Folder: Screening
Form: Medical History (7)
Data signed: (b) (4) **13 Feb 2021 00:49:54**
Generated On: 10 Jun 2021 10:07:51

Condition	PEPTIC ULCER
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-2022-1614-3765931

US3862141
Folder: Screening
Form: Medical History (8)
Data signed: (b) (4) **13 Feb 2021 00:49:54**
Generated On: 10 Jun 2021 10:07:51

Condition	INSOMNIA
Start date (dd MMM yyyy)	UN UNK 2008
Start date completely unknown	False
Condition ongoing at study entry	Yes ●
	No ○
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2008
Start Year (derived)	2008
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-3765932

US3862141
Folder: Screening
Form: Medical History (9)
Data signed: (b) (4) **13 Feb 2021 00:49:54**
Generated On: 10 Jun 2021 10:07:51

Condition	ATRIAL FIBRILLATION
Start date (dd MMM yyyy)	UN UNK 2004
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 2004
Start Year (derived)	2004
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-3765933

US3862141
Folder: Screening
Form: Medical History (10)
Data signed: (b) (4) **13 Feb 2021 00:49:54**
Generated On: 10 Jun 2021 10:07:51

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

FDA-CBER-2022-1614-3765934

US3862141
Folder: Screening
Form: Vital Signs
Data signed: (b) (4) **13 Feb 2021 00:49:54**
Generated On: 10 Jun 2021 10:07:51

Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	08 SEP 2020
Time of assessment *(00:00-23:59)*	11:51 (24 HR)
Vital Signs Date and Time (derived)	08 SEP 2020 11:51
Height *(xxx.x)*	159 cm
Weight *(xxx.x)*	185.5 lb
BMI *(xxx.x)*	33.35239 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-2022-1614-3765935

US3862141
Folder: Screening
Form: Physical Examination
Data signed: (b) (4) **13 Feb 2021 00:49:54**
Generated On: 10 Jun 2021 10:07:51

Was the physical examination performed?	Yes ☑ No ☐
Date of examination *(dd MMM yyyy)*	8 SEP 2020

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

FDA-CBER-2022-1614-3765936

US3862141
Folder: Screening
Form: Pregnancy Test
Data signed: (b) (4) **13 Feb 2021 00:49:54**
Generated On: 10 Jun 2021 10:07:51

Was the pregnancy test performed?	Yes ☐ No ☐
Date of test *(dd MMM yyyy)*	
Test performed	Urine ☐ Serum ☐
Result	Positive ☐ Negative ☐
Was FSH sample collected?	Yes ☐ No ☐
Collection date	
Collection time	
Collection date and time (derived)	

FDA-CBER-2022-1614-3765937

US3862141
Folder: Screening
Form: Risk of Exposure
Data signed: (b) (4) **13 Feb 2021 00:49:54**
Generated On: 10 Jun 2021 10:07:51

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-2022-1614-3765938

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

US3862141
Folder: Visit 1 Day 1
Form: Visit Date
Data signed: (b) (4) **13 Feb 2021 00:49:54**
Generated On: 10 Jun 2021 10:07:51

Was this visit performed?	Yes ☑ No ☐
Visit date (dd MMM yyyy)	08 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ☑
Folder OID	VISIT1

FDA-CBER-2022-1614-3765940

US3862141
Folder: Visit 1 Day 1
Form: Randomization
Data signed: (b) (4) **13 Feb 2021 00:49:54**
Generated On: 10 Jun 2021 10:07:51

What was the date of randomization? *(dd MMM yyyy)*	08 SEP 2020
What was the participant's randomization number?	190076
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-2022-1614-3765941

US3862141
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Data signed: (b) (4) **13 Feb 2021 00:49:54**
Generated On: 10 Jun 2021 10:07:51

Height	ND - Not Done
Weight	ND - Not Done

FDA-CBER-2022-1614-3765942

US3862141
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Data signed: (b) (4) **13 Feb 2021 00:49:54**
Generated On: 10 Jun 2021 10:07:51

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)*	08 SEP 2020
Time of assessment *(00:00-23:59)*	11:51 (24 HR)
Vital Signs Date and Time (derived)	08 SEP 2020 11:51
Temperature *(xxx.x)*	98.6 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	60 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	68 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-3765943

US3862141
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Data signed: (b) (4) **13 Feb 2021 00:49:54**
Generated On: 10 Jun 2021 10:07:51

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)*	8 SEP 2020
Time of assessment *(00:00-23:59)*	13:15 (24 HR)
Vital Signs Date and Time (derived)	8 SEP 2020 13:15
Temperature *(xxx.x)*	98.4 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	65 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	165 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	80 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-3765944

US3862141
Folder: Visit 1 Day 1
Form: Physical Examination
Data signed: (b) (4) **13 Feb 2021 00:49:54**
Generated On: 10 Jun 2021 10:07:51

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-2022-1614-3765945

US3862141
Folder: Visit 1 Day 1
Form: Pregnancy Test
Data signed: (b) (4) **13 Feb 2021 00:49:54**
Generated On: 10 Jun 2021 10:07:51

Was the pregnancy test performed?	Yes ☐ No ☐
Date of test *(dd MMM yyyy)*	
Test performed	Urine ☐ Serum ☐
Result	Positive ☐ Negative ☐
Was FSH sample collected?	Yes ☐ No ☐
Collection date	
Collection time	
Collection date and time (derived)	

FDA-CBER-2022-1614-3765946

US3862141
Folder: Visit 1 Day 1
Form: Exposure
Data signed: (b) (4) **13 Feb 2021 00:49:54**
Generated On: 10 Jun 2021 10:07:51

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)*	08 SEP 2020
What was the treatment time? *(00:00-23:59)*	12:45 (24 HR)
Treatment Date and Time (derived)	08 SEP 2020 12:45
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-2022-1614-3765947

US3862141
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Data signed: (b) (4) **13 Feb 2021 00:49:54**
Generated On: 10 Jun 2021 10:07:51

Was the sample collected?	Yes ☑ No ☐
Collection date *(dd MMM yyyy)*	08 SEP 2020
Collection time *(00:00-23:59)*	12:11 (24 HR)
Collection date and time (derived)	08 SEP 2020 12:11

FDA-CBER-2022-1614-3765948

US3862141
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab
Data signed: (b) (4) **13 Feb 2021 00:49:54**
Generated On: 10 Jun 2021 10:07:51

Collection date *(dd MMM yyyy)*			08 SEP 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:52	08 SEP 2020 12:52
Nasopharyngeal Swab 2	No		

FDA-CBER-2022-1614-3765949

US3862141
Folder: Visit 1 Day 1
Form: Continuing
Data signed: (b) (4) **13 Feb 2021 00:49:54**
Generated On: 10 Jun 2021 10:07:51

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

FDA-CBER-2022-1614-3765950

US3862141
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 10:07:51

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	08 SEP 2020 13:10
PC Open Date & Time	08 SEP 2020 13:05
PC Close Date & Time	08 SEP 2020 15:35

FDA-CBER-2022-1614-3765951

US3862141
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 10:07:51

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**	97.8 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	08 SEP 2020 17:46
PC Open Date & Time	08 SEP 2020 16:30
PC Close Date & Time	09 SEP 2020 11:59

FDA-CBER-2022-1614-3765952

US3862141
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 10:07:51

TIMEPOINT	DAY 2

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	97.4 °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	09 SEP 2020 14:49
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

FDA-CBER-2022-1614-3765953

US3862141
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 10:07:51

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	10 SEP 2020 13:56
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3862141
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 10:07:51

TIMEPOINT	DAY 4

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	98.2 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	11 SEP 2020 12:39
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

FDA-CBER-2022-1614-3765955

US3862141
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 10:07:51

TIMEPOINT	DAY 5

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	97.6 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	12 SEP 2020 14:30
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3862141
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 10:07:51

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**	97.9 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	13 SEP 2020 16:02
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

FDA-CBER-2022-1614-3765957

US3862141
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 10:07:51

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	14 SEP 2020 12:51
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

FDA-CBER-2022-1614-3765958

US3862141
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 10:07:51

TIMEPOINT	DAY 1, 30 MINUTES AFTER VACCINATION (AT STUDY CLINIC)
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	08 SEP 2020 13:11
PC Open Date & Time	08 SEP 2020 13:05
PC Close Date & Time	08 SEP 2020 15:35

FDA-CBER-2022-1614-3765959

US3862141
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 10:07:51

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	08 SEP 2020 17:46
PC Open Date & Time	08 SEP 2020 16:30
PC Close Date & Time	09 SEP 2020 11:59

FDA-CBER-2022-1614-3765960

US3862141
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 10:07:51

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	09 SEP 2020 14:50
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

FDA-CBER-2022-1614-3765961

US3862141
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 10:07:51

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	10 SEP 2020 13:57
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3862141
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 10:07:51

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	11 SEP 2020 12:40
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

FDA-CBER-2022-1614-3765963

US3862141
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 10:07:51

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	12 SEP 2020 14:31
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

FDA-CBER-2022-1614-3765964

US3862141
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 10:07:51

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	13 SEP 2020 16:03
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

FDA-CBER-2022-1614-3765965

US3862141
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 10:07:51

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	14 SEP 2020 12:52
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

FDA-CBER-2022-1614-3765966

TIMEPOINT	DAY 1, 30 MINUTES AFTER VACCINATION (AT STUDY CLINIC)
HEADACHE	None ■ No interference with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
FATIGUE	None ■ No interference with activity ☐ Some interference with activity ☐ Significant; prevents daily activity ☐
MUSCLE ACHES ALL OVER BODY	None ■ No interference with activity ☐ Some interference with activity ☐ Significant; prevents daily activity ☐
JOINT ACHES IN SEVERAL JOINTS	None ■ No interference with activity ☐ Some interference with activity ☐ Significant; prevents daily activity ☐
NAUSEA/VOMITING	None ■ No interference with activity or 1-2 episodes/24 hours ☐ Some interference with activity or >2 episodes/24 hours ☐ Prevents daily activity, requires outpatient IV hydration ☐
CHILLS	None ■ No interference with activity ☐ Some interference with activity not requiring medical attention ☐ Prevents daily activity and requires medical attention ☐

FDA-CBER-2022-1614-3765967

US3862141
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 10:07:51

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ☑ Yes ☐
PC Time stamp	08 SEP 2020 13:12
PC Open Date & Time	08 SEP 2020 13:05
PC Close Date & Time	08 SEP 2020 15:35

FDA-CBER-2022-1614-3765968

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)
HEADACHE	None ■ No interference with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
FATIGUE	None ■ No interference with activity ☐ Some interference with activity ☐ Significant; prevents daily activity ☐
MUSCLE ACHES ALL OVER BODY	None ■ No interference with activity ☐ Some interference with activity ☐ Significant; prevents daily activity ☐
JOINT ACHES IN SEVERAL JOINTS	None ■ No interference with activity ☐ Some interference with activity ☐ Significant; prevents daily activity ☐
NAUSEA/VOMITING	None ■ No interference with activity or 1-2 episodes/24 hours ☐ Some interference with activity or >2 episodes/24 hours ☐ Prevents daily activity, requires outpatient IV hydration ☐
CHILLS	None ■ No interference with activity ☐ Some interference with activity not requiring medical attention ☐ Prevents daily activity and requires medical attention ☐

FDA-CBER-2022-1614-3765969

US3862141
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 10:07:51

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	08 SEP 2020 17:47
PC Open Date & Time	08 SEP 2020 16:30
PC Close Date & Time	09 SEP 2020 11:59

FDA-CBER-2022-1614-3765970

US3862141
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 10:07:51

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-2022-1614-3765971

US3862141
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 10:07:51

	Yes
PC Time stamp	09 SEP 2020 14:51
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

FDA-CBER-2022-1614-3765972

US3862141
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 10:07:51

TIMEPOINT	DAY 3
HEADACHE	None ■ No interference with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
FATIGUE	None ■ No interference with activity ☐ Some interference with activity ☐ Significant; prevents daily activity ☐
MUSCLE ACHES ALL OVER BODY	None ■ No interference with activity ☐ Some interference with activity ☐ Significant; prevents daily activity ☐
JOINT ACHES IN SEVERAL JOINTS	None ■ No interference with activity ☐ Some interference with activity ☐ Significant; prevents daily activity ☐
NAUSEA/VOMITING	None ■ No interference with activity or 1-2 episodes/24 hours ☐ Some interference with activity or >2 episodes/24 hours ☐ Prevents daily activity, requires outpatient IV hydration ☐
CHILLS	None ■ No interference with activity ☐ Some interference with activity not requiring medical attention ☐ Prevents daily activity and requires medical attention ☐
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■

FDA-CBER-2022-1614-3765973

US3862141
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 10:07:51

	Yes ☐
PC Time stamp	10 SEP 2020 13:58
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

FDA-CBER-2022-1614-3765974

US3862141
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 10:07:51

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-2022-1614-3765975

US3862141
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 10:07:51

	Yes ☐
PC Time stamp	11 SEP 2020 12:40
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

FDA-CBER-2022-1614-3765976

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

FDA-CBER-2022-1614-3765977

	Yes ☐
PC Time stamp	12 SEP 2020 14:32
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3862141
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 10:07:51

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-2022-1614-3765979

US3862141
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 10:07:51

	Yes ☐
PC Time stamp	13 SEP 2020 16:04
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

FDA-CBER-2022-1614-3765980

US3862141
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 10:07:51

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-2022-1614-3765981

US3862141
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 10:07:51

	Yes ☐
PC Time stamp	14 SEP 2020 12:52
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

FDA-CBER-2022-1614-3765982

US3862141
Folder: Safety Call Day 8 (1)
Form: Safety Call
Data signed: (b) (4) **13 Feb 2021 00:49:53**
Generated On: 10 Jun 2021 10:07:51

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	15 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-2022-1614-3765983

US3862141
Folder: Safety Call Day 8 (1)
Form: Continuing
Data signed: (b) (4) **13 Feb 2021 00:49:53**
Generated On: 10 Jun 2021 10:07:51

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

FDA-CBER-2022-1614-3765984

US3862141
Folder: Safety Call Day 15 (1)
Form: Safety Call
Data signed: (b) (4) **13 Feb 2021 00:49:53**
Generated On: 10 Jun 2021 10:07:51

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

FDA-CBER-2022-1614-3765985

US3862141
Folder: Safety Call Day 15 (1)
Form: Continuing
Data signed: (b) (4) **13 Feb 2021 00:49:53**
Generated On: 10 Jun 2021 10:07:51

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

FDA-CBER-2022-1614-3765986

US3862141
Folder: Safety Call Day 22 (1)
Form: Safety Call
Data signed: (b) (4) **13 Feb 2021 00:49:53**
Generated On: 10 Jun 2021 10:07:51

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	29 SEP 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments	
If Contact Not Made, please provide Comments	

FDA-CBER-2022-1614-3765987

US3862141
Folder: Safety Call Day 22 (1)
Form: Continuing
Data signed: (b) (4) **13 Feb 2021 00:49:53**
Generated On: 10 Jun 2021 10:07:51

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

FDA-CBER-2022-1614-3765988

US3862141
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Data signed: (b) (4) **13 Feb 2021 00:49:54**
Generated On: 10 Jun 2021 10:07:51

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	6 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	VISIT2

FDA-CBER-2022-1614-3765989

US3862141
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Data signed: (b) (4) **13 Feb 2021 00:49:54**
Generated On: 10 Jun 2021 10:07:51

Timepoint	Pre-Dose ■ Post-Dose ☐
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	6 OCT 2020
Time of assessment *(00:00-23:59)*	11:15 (24 HR)
Vital Signs Date and Time (derived)	6 OCT 2020 11:15
Temperature *(xxx.x)*	098.3 F
Route of measurement	Oral ☐ Axillary ☐ Other ■
If Other, specify	TEMPORAL
Pulse *(xxx)*	065 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	018 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	145 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	072 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-3765990

US3862141
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Data signed: (b) (4) **13 Feb 2021 00:49:54**
Generated On: 10 Jun 2021 10:07:51

Timepoint	Pre-Dose ☐ Post-Dose ■
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	6 OCT 2020
Time of assessment *(00:00-23:59)*	13:22 (24 HR)
Vital Signs Date and Time (derived)	6 OCT 2020 13:22
Temperature *(xxx.x)*	097.8 F
Route of measurement	Oral ☐ Axillary ☐ Other ■
If Other, specify	TEMPORAL
Pulse *(xxx)*	064 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	018 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	063 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-3765991

US3862141
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Data signed: (b) (4) **13 Feb 2021 00:49:54**
Generated On: 10 Jun 2021 10:07:51

Was the physical examination performed?	Yes ☑ No ☐
Date of examination *(dd MMM yyyy)*	6 OCT 2020

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

FDA-CBER-2022-1614-3765992

US3862141
Folder: Visit 2 Day 29 (1)
Form: Exposure
Data signed: (b) (4) **13 Feb 2021 00:49:54**
Generated On: 10 Jun 2021 10:07:51

Was study treatment given?	Yes ■ No ☐
If No, reason not given	Participant declined due to Adverse Event ☐ Physician withheld dose due to Adverse Event ☐ Death ☐ Lost To Follow-Up ☐ Physician Decision ☐ Pregnancy ☐ Protocol Deviation ☐ Study Terminated by Sponsor ☐ Withdrawal of Consent by Participant ☐ Confirmed COVID-19 ☐ Other ☐
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment?	MRNA-1273 OR PLACEBO
What was the treatment date? *(dd MMM yyyy)*	6 OCT 2020
What was the treatment time? *(00:00-23:59)*	12:37 (24 HR)
Treatment Date and Time (derived)	6 OCT 2020 12:37
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-2022-1614-3765993

US3862141
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **13 Feb 2021 00:49:54**
Generated On: 10 Jun 2021 10:07:51

Was the sample collected?	Yes ☑ No ☐
Collection date *(dd MMM yyyy)*	6 OCT 2020
Collection time *(00:00-23:59)*	12:00 (24 HR)
Collection date and time (derived)	6 OCT 2020 12:00

FDA-CBER-2022-1614-3765994

US3862141
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab
Data signed: (b) (4) **13 Feb 2021 00:49:54**
Generated On: 10 Jun 2021 10:07:51

Collection date *(dd MMM yyyy)* 6 OCT 2020

Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	No		
Nasopharyngeal Swab 2	Yes	11:52	6 OCT 2020 11:52

FDA-CBER-2022-1614-3765995

US3862141
Folder: Visit 2 Day 29 (1)
Form: Continuing
Data signed: (b) (4) **13 Feb 2021 00:49:54**
Generated On: 10 Jun 2021 10:07:51

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

FDA-CBER-2022-1614-3765996

US3862141
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 10:07:51

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**	98.2 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	06 OCT 2020 13:05
PC Open Date & Time	06 OCT 2020 12:57
PC Close Date & Time	06 OCT 2020 15:27

FDA-CBER-2022-1614-3765997

US3862141
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 10:07:51

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.5 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	06 OCT 2020 18:47
PC Open Date & Time	06 OCT 2020 16:22
PC Close Date & Time	07 OCT 2020 11:59

FDA-CBER-2022-1614-3765998

US3862141
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 10:07:51

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	07 OCT 2020 12:22
PC Open Date & Time	07 OCT 2020 12:00
PC Close Date & Time	08 OCT 2020 11:59

US3862141
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 10:07:51

TIMEPOINT	DAY 3

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	97.7 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ■ No ☐
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	08 OCT 2020 12:03
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3862141
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 10:07:51

TIMEPOINT	DAY 4

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.2 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	09 OCT 2020 13:50
PC Open Date & Time	09 OCT 2020 12:00
PC Close Date & Time	10 OCT 2020 11:59

US3862141
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 10:07:51

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**	98.4 °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	10 OCT 2020 12:41
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

US3862141
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 10:07:51

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**	97.4 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	11 OCT 2020 13:36
PC Open Date & Time	11 OCT 2020 12:00
PC Close Date & Time	12 OCT 2020 11:59

FDA-CBER-2022-1614-3766003

US3862141
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 10:07:51

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**	97.2 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	12 OCT 2020 12:24
PC Open Date & Time	12 OCT 2020 12:00
PC Close Date & Time	13 OCT 2020 11:59

FDA-CBER-2022-1614-3766004

US3862141
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 10:07:51

TIMEPOINT	DAY 1, 30 MINUTES AFTER VACCINATION (AT STUDY CLINIC)
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ● Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ●
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ●
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ● Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	06 OCT 2020 13:27
PC Open Date & Time	06 OCT 2020 12:57
PC Close Date & Time	06 OCT 2020 15:27

FDA-CBER-2022-1614-3766005

US3862141
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 10:07:51

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	06 OCT 2020 18:48
PC Open Date & Time	06 OCT 2020 16:22
PC Close Date & Time	07 OCT 2020 11:59

FDA-CBER-2022-1614-3766006

US3862141
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 10:07:51

TIMEPOINT	DAY 2
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ☐ Does not interfere with activity ■ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	07 OCT 2020 12:23
PC Open Date & Time	07 OCT 2020 12:00
PC Close Date & Time	08 OCT 2020 11:59

FDA-CBER-2022-1614-3766007

US3862141
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 10:07:51

TIMEPOINT	DAY 3
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ☐ Does not interfere with activity ■ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	08 OCT 2020 12:03
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3862141
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 10:07:51

TIMEPOINT	DAY 4
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	09 OCT 2020 13:50
PC Open Date & Time	09 OCT 2020 12:00
PC Close Date & Time	10 OCT 2020 11:59

FDA-CBER-2022-1614-3766009

US3862141
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 10:07:51

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	10 OCT 2020 12:42
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

FDA-CBER-2022-1614-3766010

US3862141
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 10:07:51

TIMEPOINT	DAY 6
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ● Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ●
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ●
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ● Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	11 OCT 2020 13:36
PC Open Date & Time	11 OCT 2020 12:00
PC Close Date & Time	12 OCT 2020 11:59

FDA-CBER-2022-1614-3766011

US3862141
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 10:07:51

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	12 OCT 2020 12:24
PC Open Date & Time	12 OCT 2020 12:00
PC Close Date & Time	13 OCT 2020 11:59

TIMEPOINT	DAY 1, 30 MINUTES AFTER VACCINATION (AT STUDY CLINIC)
HEADACHE	None ■ No interference with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
FATIGUE	None ■ No interference with activity ☐ Some interference with activity ☐ Significant; prevents daily activity ☐
MUSCLE ACHES ALL OVER BODY	None ■ No interference with activity ☐ Some interference with activity ☐ Significant; prevents daily activity ☐
JOINT ACHES IN SEVERAL JOINTS	None ■ No interference with activity ☐ Some interference with activity ☐ Significant; prevents daily activity ☐
NAUSEA/VOMITING	None ■ No interference with activity or 1-2 episodes/24 hours ☐ Some interference with activity or >2 episodes/24 hours ☐ Prevents daily activity, requires outpatient IV hydration ☐
CHILLS	None ■ No interference with activity ☐ Some interference with activity not requiring medical attention ☐ Prevents daily activity and requires medical attention ☐

FDA-CBER-2022-1614-3766013

US3862141
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 10:07:51

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	06 OCT 2020 13:28
PC Open Date & Time	06 OCT 2020 12:57
PC Close Date & Time	06 OCT 2020 15:27

FDA-CBER-2022-1614-3766014

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)
HEADACHE	None ■
	No interference with activity ☐
	Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity ☐
	Any use of prescription pain reliever or prevents daily activity ☐
FATIGUE	None ■
	No interference with activity ☐
	Some interference with activity ☐
	Significant; prevents daily activity ☐
MUSCLE ACHES ALL OVER BODY	None ■
	No interference with activity ☐
	Some interference with activity ☐
	Significant; prevents daily activity ☐
JOINT ACHES IN SEVERAL JOINTS	None ■
	No interference with activity ☐
	Some interference with activity ☐
	Significant; prevents daily activity ☐
NAUSEA/VOMITING	None ■
	No interference with activity or 1-2 episodes/24 hours ☐
	Some interference with activity or >2 episodes/24 hours ☐
	Prevents daily activity, requires outpatient IV hydration ☐
CHILLS	None ■
	No interference with activity ☐
	Some interference with activity not requiring medical attention ☐
	Prevents daily activity and requires medical attention ☐

FDA-CBER-2022-1614-3766015

US3862141
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 10:07:51

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	06 OCT 2020 18:49
PC Open Date & Time	06 OCT 2020 16:22
PC Close Date & Time	07 OCT 2020 11:59

FDA-CBER-2022-1614-3766016

US3862141
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 10:07:51

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-2022-1614-3766017

US3862141
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 10:07:51

	Yes ☐
PC Time stamp	07 OCT 2020 12:23
PC Open Date & Time	07 OCT 2020 12:00
PC Close Date & Time	08 OCT 2020 11:59

FDA-CBER-2022-1614-3766018

US3862141
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 10:07:51

TIMEPOINT	DAY 3
HEADACHE	None ■
	No interference with activity ☐
	Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity ☐
	Any use of prescription pain reliever or prevents daily activity ☐
FATIGUE	None ■
	No interference with activity ☐
	Some interference with activity ☐
	Significant; prevents daily activity ☐
MUSCLE ACHES ALL OVER BODY	None ■
	No interference with activity ☐
	Some interference with activity ☐
	Significant; prevents daily activity ☐
JOINT ACHES IN SEVERAL JOINTS	None ■
	No interference with activity ☐
	Some interference with activity ☐
	Significant; prevents daily activity ☐
NAUSEA/VOMITING	None ■
	No interference with activity or 1-2 episodes/24 hours ☐
	Some interference with activity or >2 episodes/24 hours ☐
	Prevents daily activity, requires outpatient IV hydration ☐
CHILLS	None ■
	No interference with activity ☐
	Some interference with activity not requiring medical attention ☐
	Prevents daily activity and requires medical attention ☐
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■

FDA-CBER-2022-1614-3766019

US3862141
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 10:07:51

	Yes ☐
PC Time stamp	08 OCT 2020 12:06
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

FDA-CBER-2022-1614-3766020

US3862141
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 10:07:51

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-2022-1614-3766021

US3862141
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 10:07:51

	Yes ☐
PC Time stamp	09 OCT 2020 13:51
PC Open Date & Time	09 OCT 2020 12:00
PC Close Date & Time	10 OCT 2020 11:59

FDA-CBER-2022-1614-3766022

US3862141
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 10:07:51

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

FDA-CBER-2022-1614-3766023

US3862141
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 10:07:51

	Yes ☐
PC Time stamp	10 OCT 2020 12:42
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

FDA-CBER-2022-1614-3766024

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-2022-1614-3766025

US3862141
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 10:07:51

	Yes
PC Time stamp	11 OCT 2020 13:36
PC Open Date & Time	11 OCT 2020 12:00
PC Close Date & Time	12 OCT 2020 11:59

FDA-CBER-2022-1614-3766026

US3862141
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 10:07:51

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-2022-1614-3766027

US3862141
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 10:07:51

	Yes ☐
PC Time stamp	12 OCT 2020 12:25
PC Open Date & Time	12 OCT 2020 12:00
PC Close Date & Time	13 OCT 2020 11:59

FDA-CBER-2022-1614-3766028

US3862141
Folder: Safety Call Day 36 (1)
Form: Safety Call
Data signed: (b) (4) **13 Feb 2021 00:49:53**
Generated On: 10 Jun 2021 10:07:51

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	13 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-2022-1614-3766029

US3862141
Folder: Safety Call Day 36 (1)
Form: Continuing
Data signed: (b) (4) **13 Feb 2021 00:49:53**
Generated On: 10 Jun 2021 10:07:51

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

FDA-CBER-2022-1614-3766030

US3862141
Folder: Safety Call Day 43 (1)
Form: Safety Call
Data signed: (b) (4) **13 Feb 2021 00:49:53**
Generated On: 10 Jun 2021 10:07:51

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	20 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-2022-1614-3766031

US3862141
Folder: Safety Call Day 43 (1)
Form: Continuing
Data signed: (b) (4) **13 Feb 2021 00:49:53**
Generated On: 10 Jun 2021 10:07:51

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

FDA-CBER-2022-1614-3766032

US3862141
Folder: Safety Call Day 50 (1)
Form: Safety Call
Data signed: (b) (4) **13 Feb 2021 00:49:53**
Generated On: 10 Jun 2021 10:07:51

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	27 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-2022-1614-3766033

US3862141
Folder: Safety Call Day 50 (1)
Form: Continuing
Data signed: (b) (4) **13 Feb 2021 00:49:53**
Generated On: 10 Jun 2021 10:07:51

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

FDA-CBER-2022-1614-3766034

US3862141
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Data signed: (b) (4) **13 Feb 2021 00:49:54**
Generated On: 10 Jun 2021 10:07:51

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	3 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	VISIT3

FDA-CBER-2022-1614-3766035

US3862141
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Data signed: (b) (4) **13 Feb 2021 00:49:54**
Generated On: 10 Jun 2021 10:07:51

Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	3 NOV 2020
Time of assessment *(00:00-23:59)*	11:06 (24 HR)
Vital Signs Date and Time (derived)	3 NOV 2020 11:06
Temperature *(xxx.x)*	098.0 F
Route of measurement	Oral ☐ Axillary ☐ Other ■
If Other, specify	TEMPORAL
Pulse *(xxx)*	060 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	012 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	060 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

FDA-CBER-2022-1614-3766036

US3862141
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Data signed: (b) (4) **13 Feb 2021 00:49:54**
Generated On: 10 Jun 2021 10:07:51

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-2022-1614-3766037

US3862141
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **13 Feb 2021 00:49:54**
Generated On: 10 Jun 2021 10:07:51

Was the sample collected?	Yes ☑ No ☐
Collection date *(dd MMM yyyy)*	3 NOV 2020
Collection time *(00:00-23:59)*	11:45 (24 HR)
Collection date and time (derived)	3 NOV 2020 11:45

FDA-CBER-2022-1614-3766038

US3862141
Folder: Visit 3 Day 57 (1)
Form: Continuing
Data signed: (b) (4) **13 Feb 2021 00:49:54**
Generated On: 10 Jun 2021 10:07:51

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

FDA-CBER-2022-1614-3766039

US3862141
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:07:51

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	09 NOV 2020 14:35:30
Patient Cloud Open Date & Time	08 NOV 2020 00:01
Patient Cloud Close Date & Time	12 NOV 2020 23:59

FDA-CBER-2022-1614-3766040

US3862141
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:07:51

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	16 NOV 2020 10:41:34
Patient Cloud Open Date & Time	15 NOV 2020 00:01
Patient Cloud Close Date & Time	19 NOV 2020 23:59

FDA-CBER-2022-1614-3766041

US3862141
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:07:51

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 NOV 2020 16:05:29
Patient Cloud Open Date & Time	19 NOV 2020 00:01
Patient Cloud Close Date & Time	23 NOV 2020 23:59

US3862141
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:07:51

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	28 NOV 2020 12:02:04
Patient Cloud Open Date & Time	26 NOV 2020 00:01
Patient Cloud Close Date & Time	30 NOV 2020 23:59

FDA-CBER-2022-1614-3766043

US3862141
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:07:51

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	05 DEC 2020 10:53:32
Patient Cloud Open Date & Time	03 DEC 2020 00:01
Patient Cloud Close Date & Time	07 DEC 2020 23:59

US3862141
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:07:51

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 DEC 2020 16:12:13
Patient Cloud Open Date & Time	10 DEC 2020 00:01
Patient Cloud Close Date & Time	14 DEC 2020 23:59

FDA-CBER-2022-1614-3766045

US3862141
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:07:51

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 DEC 2020 12:10:22
Patient Cloud Open Date & Time	17 DEC 2020 00:01
Patient Cloud Close Date & Time	21 DEC 2020 23:59

FDA-CBER-2022-1614-3766046

US3862141
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:07:51

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	25 DEC 2020 13:17:37
Patient Cloud Open Date & Time	24 DEC 2020 00:01
Patient Cloud Close Date & Time	28 DEC 2020 23:59

US3862141
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:07:51

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 JAN 2021 09:02:00
Patient Cloud Open Date & Time	31 DEC 2020 00:01
Patient Cloud Close Date & Time	04 JAN 2021 23:59

FDA-CBER-2022-1614-3766048

US3862141
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:07:51

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 JAN 2021 18:32:01
Patient Cloud Open Date & Time	07 JAN 2021 00:01
Patient Cloud Close Date & Time	11 JAN 2021 23:59

FDA-CBER-2022-1614-3766049

US3862141
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:07:51

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 JAN 2021 20:10:46
Patient Cloud Open Date & Time	14 JAN 2021 00:01
Patient Cloud Close Date & Time	18 JAN 2021 23:59

US3862141
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:07:51

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 JAN 2021 12:23:47
Patient Cloud Open Date & Time	21 JAN 2021 00:01
Patient Cloud Close Date & Time	25 JAN 2021 23:59

FDA-CBER-2022-1614-3766051

US3862141
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:07:51

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 JAN 2021 18:00:22
Patient Cloud Open Date & Time	28 JAN 2021 00:01
Patient Cloud Close Date & Time	01 FEB 2021 23:59

FDA-CBER-2022-1614-3766052

US3862141
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:07:51

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 FEB 2021 10:03:48
Patient Cloud Open Date & Time	04 FEB 2021 00:01
Patient Cloud Close Date & Time	08 FEB 2021 23:59

US3862141
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:07:51

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 FEB 2021 13:40:27
Patient Cloud Open Date & Time	11 FEB 2021 00:01
Patient Cloud Close Date & Time	15 FEB 2021 23:59

FDA-CBER-2022-1614-3766054

US3862141
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:07:51

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 FEB 2021 11:13:56
Patient Cloud Open Date & Time	18 FEB 2021 00:01
Patient Cloud Close Date & Time	22 FEB 2021 23:59

FDA-CBER-2022-1614-3766055

US3862141
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:07:51

TIMEPOINT	DAY 173
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	26 FEB 2021 15:43:31
Patient Cloud Open Date & Time	25 FEB 2021 00:01
Patient Cloud Close Date & Time	01 MAR 2021 23:59

US3862141
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:07:51

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 MAR 2021 11:20:18
Patient Cloud Open Date & Time	04 MAR 2021 00:01
Patient Cloud Close Date & Time	08 MAR 2021 23:59

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		03 MAR 2021 16:49:42

US3862141
Folder: Safety Call Day 85 (1)
Form: Safety Call
Data signed: (b) (4) **05 Mar 2021 22:31:17**
Generated On: 10 Jun 2021 10:07:51

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	01 DEC 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments	
If Contact Not Made, please provide Comments	

FDA-CBER-2022-1614-3766059

US3862141
Folder: Safety Call Day 85 (1)
Form: Continuing
Data signed: (b) (4) **05 Mar 2021 22:31:17**
Generated On: 10 Jun 2021 10:07:51

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

FDA-CBER-2022-1614-3766060

US3862141
Folder: Safety Call Day 119 (1)
Form: Safety Call
Data signed: (b) (4) **02 Apr 2021 14:26:25**
Generated On: 10 Jun 2021 10:07:51

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*	

FDA-CBER-2022-1614-3766061

US3862141
Folder: Safety Call Day 119 (1)
Form: Continuing
Data signed: (b) (4) **02 Apr 2021 14:26:25**
Generated On: 10 Jun 2021 10:07:51

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

FDA-CBER-2022-1614-3766062

US3862141
Folder: Safety Call Day 149 (1)
Form: Safety Call
Data signed: (b) (4) **02 Apr 2021 14:27:13**
Generated On: 10 Jun 2021 10:07:51

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*	

FDA-CBER-2022-1614-3766063

US3862141
Folder: Safety Call Day 149 (1)
Form: Continuing
Data signed: (b) (4) **02 Apr 2021 14:26:25**
Generated On: 10 Jun 2021 10:07:51

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

FDA-CBER-2022-1614-3766064

US3862141
Folder: Safety Call Day 179 (1)
Form: Safety Call
Data signed: (b) (4) **02 Apr 2021 14:27:13**
Generated On: 10 Jun 2021 10:07:51

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	5 MAR 2021
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments	
If Contact Not Made, please provide Comments	

FDA-CBER-2022-1614-3766065

US3862141
Folder: Safety Call Day 179 (1)
Form: Continuing
Data signed: (b) (4) **02 Apr 2021 14:27:13**
Generated On: 10 Jun 2021 10:07:51

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

FDA-CBER-2022-1614-3766066

US3862141
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 10 Jun 2021 10:07:51

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

FDA-CBER-2022-1614-3766067

US3862141
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 10:07:51

Were vital signs assessed?	Yes ☐ No ☐
Date of assessment *(dd MMM yyyy)*	
Time of assessment *(00:00-23:59)*	
Vital Signs Date and Time (derived)	
Temperature *(xxx.x)*	
Route of measurement	Oral ☐ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	
Pulse units	
Respiratory Rate *(xxx)*	
Respiratory Rate units	
Systolic Blood Pressure *(xxx)*	
Systolic Blood Pressure units	
Diastolic Blood Pressure *(xxx)*	
Diastolic Blood Pressure units	
Height (derived)	
Weight (derived)	

Was the physical examination performed? Yes ☐ No ☐

Date of examination *(dd MMM yyyy)* _____

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

Was the sample collected?	Yes ☐ No ☐
Collection date *(dd MMM yyyy)*	
Collection time *(00:00-23:59)*	
Collection date and time (derived)	

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

US3862141
Folder: Covid-19 Assessment (1)
Form: COVID-19 Contact
Generated On: 10 Jun 2021 10:07:51

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-2022-1614-3766072

Generate Next COVID-19 Assessment	Yes ☐ No ☐

US3862141
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 10 Jun 2021 10:07:51

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

FDA-CBER-2022-1614-3766074

US3862141
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 10:07:51

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

Was the sample collected?	Yes ☐ No ☐
Collection date *(dd MMM yyyy)*	
Collection time *(00:00-23:59)*	
Collection date and time (derived)	

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

US3862141
Folder: Adverse Events
Form: Adverse Events Summary
Data signed: (b) (4) **22 Mar 2021 15:17:26**
Generated On: 10 Jun 2021 10:07:51

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

If Yes, enter details on the Adverse Events form.

FDA-CBER-2022-1614-3766078

US3862141
Folder: Adverse Events
Form: Adverse Events (1)
Data signed: (b) (4) **22 Mar 2021 15:17:25**
Generated On: 10 Jun 2021 10:07:51

AEID	USA-US121-2021-MRNA-1273-P30 1000004
Adverse event	CARDIOPULMONARY ARREST
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)*	09 MAR 2021
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ■
If not Ongoing, end date *(dd MMM yyyy)*	09 MAR 2021
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ■
Is the adverse event serious?	Yes ■ No ☐
AE is serious due To (check all that apply)	
Death	True
Life threatening	True
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date *(dd MMM yyyy)*	09 MAR 2021
Hospital Discharge Date *(dd MMM yyyy)*	09 MAR 2021
Admitted to ICU?	Yes ■ No ☐ Unknown ☐

FDA-CBER-2022-1614-3766079

Number of Days in ICU	1
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ■ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ■ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product Withdrawn ☐ Not Applicable ■
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
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

CARDIOPULMONARY ARREST RELATED TO UNDERLYING MEDICAL HISTORY (CAD, ATRIAL FIBRILLATION REQUIRING ICD INSERTION)
NARRATIVE:
PI CALLED SUBJECT'S FAMILY. THE SUBJECT HAD A LEAK IN THE HOUSE AND RAN UPSTAIRS QUICKLY TO CHECK. AFTER THE RAPID MOVEMENT HIS HEART WAS RACING AND COLLAPSED LOSING CONSCIOUSNESS. HE BRIEFLY REGAINED CONSCIOUSNESS AND LOST IT AGAIN. NO OTHER COMPLAINTS, SEIZURE ACTIVITY, HOLDING CHEST.
IN THE ER, HE HAS FOUND TO BE IN VENTRICULAR FIBRILLATION, HE WAS BROUGHT BACK IN INTO RHYTHM (SINUS?) AND ADMITTED TO MICU. HE IS CURRENTLY MECHANICALLY VENTILATED AND SEDATED.
SITE WILL FOLLOW UP WITH SUBJECT AND FAMILY MEMBERS FOR HEALTH UPDATES AND REQUEST MEDICAL RECORDS.
17 MAR 2021:
DAUGHTER IN LAW WAS CONTACTED AND REPORTED THAT SUBJECT HAD ANOTHER CARDIOPULMONARY ARREST AND PASSED AWAY ON THE SAME DAY 09 MAR 2021.
MEDICAL RECORDS WILL BE REQUESTED
19MAR2021: MEDICAL RECORDS WERE REQUESTED TODAY, 19MAR2021

FDA-CBER-2022-1614-3766081

US3862141
Folder: Adverse Events
Form: Adverse Events (1)
Data signed: (b) (4) **22 Mar 2021 15:17:25**
Generated On: 10 Jun 2021 10:07:51

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

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination Summary
Data signed: (b) (4) **02 Apr 2021 14:26:25**
Generated On: 10 Jun 2021 10:07:51

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

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

FDA-CBER-2022-1614-3766083

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Data signed: (b) (4) **02 Apr 2021 14:26:24**
Generated On: 10 Jun 2021 10:07:51

Name of Medication	INSULIN
Prophylaxis	Yes ☐ No ■
Indication	DIABETES MELLITUS TYPE 2
Dose per administration	2
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ■
If dose unit is Other, specify	UNITS
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-2022-1614-3766084

	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 ■

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Data signed: (b) (4) **02 Apr 2021 14:26:24**
Generated On: 10 Jun 2021 10:07:51

Name of Medication	FUROSEMIDE
Prophylaxis	Yes ☐ No ■
Indication	CONGESTIVE HEART FAILURE
Dose per administration	40
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ■ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

FDA-CBER-2022-1614-3766086

	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 2004
Start date completely unknown	False
Ongoing?	Yes ■ No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐ No ■
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ■

Name of Medication	CARVEDILOL
Prophylaxis	Yes ☐ No ■
Indication	CONGESTIVE HEART FAILURE
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-2022-1614-3766088

	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 2004
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 ■

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Data signed: (b) (4) **02 Apr 2021 14:26:24**
Generated On: 10 Jun 2021 10:07:51

Name of Medication	LIPITOR
Prophylaxis	Yes ☐ No ■
Indication	CORONARY ARTERY DISEASE
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 ☐

FDA-CBER-2022-1614-3766090

	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 ■

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Data signed: (b) (4) **02 Apr 2021 14:26:24**
Generated On: 10 Jun 2021 10:07:51

Name of Medication	LEVOTHYROXINE
Prophylaxis	Yes ☐ No ■
Indication	HYPOTHYROIDISM
Dose per administration	0.1
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ■ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

FDA-CBER-2022-1614-3766092

	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 1995
Start date completely unknown	False
Ongoing?	Yes ■
	No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

Name of Medication	NEPHRO VITAMIN WITH ASCORBIC ACID, NIACINAMIDE, PANTOTHENIC ACID, PYRIDOXINE HYDROCHOLRIDE, RIBOFLAVIN, THIAMINE MONONITRATE, FOLIC ACID, D-BIOTIN, AND CYANOCOBALAMIN
Prophylaxis	Yes ■ No ☐
Indication	SUPPLEMENT
Dose per administration	1
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ■ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ■ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐

If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐ Respiratory (Inhalation) ☐ Intralesional ☐ Intraperiteoneal ☐ Nasal ☐ Vaginal ☐ Rectal ☐ Intravenous ☐ Intravenous Bolus ☐ Intravenous Drip ☐ Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	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)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ■

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Data signed: (b) (4) **02 Apr 2021 14:26:24**
Generated On: 10 Jun 2021 10:07:51

Name of Medication	ALPRAZOLAM
Prophylaxis	Yes ☐ No ■
Indication	INSOMNIA
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-2022-1614-3766096

	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 2008
Start date completely unknown	False
Ongoing?	Yes ■
	No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Data signed: (b) (4) **02 Apr 2021 14:26:24**
Generated On: 10 Jun 2021 10:07:51

Name of Medication	ASPIRIN
Prophylaxis	Yes ☐ No ■
Indication	CORONARY ARTERY DISEASE
Dose per administration	81
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ■ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

FDA-CBER-2022-1614-3766098

	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 ■

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Data signed: (b) (4) **02 Apr 2021 14:26:24**
Generated On: 10 Jun 2021 10:07:51

Name of Medication	ALLOPURINOL
Prophylaxis	Yes ☐ No ■
Indication	GOUT
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 ☐

FDA-CBER-2022-1614-3766100

	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)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Data signed: (b) (4) **02 Apr 2021 14:26:24**
Generated On: 10 Jun 2021 10:07:51

Name of Medication	VITAMIN D3
Prophylaxis	Yes ■ No ☐
Indication	SUPPLEMENT
Dose per administration	2000
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-2022-1614-3766102

	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)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Data signed: (b) (4) **02 Apr 2021 14:26:24**
Generated On: 10 Jun 2021 10:07:51

Name of Medication	PANTOPRAZOLE
Prophylaxis	Yes ☐ No ■
Indication	PEPTIC ULCER
Dose per administration	40
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ■ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

FDA-CBER-2022-1614-3766104

	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)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Data signed: (b) (4) **02 Apr 2021 14:26:24**
Generated On: 10 Jun 2021 10:07:51

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

FDA-CBER-2022-1614-3766106

	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 JAN 2020
Start date completely unknown	False
Ongoing?	Yes ■
	No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Data signed: (b) (4) **02 Apr 2021 14:26:24**
Generated On: 10 Jun 2021 10:07:51

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

FDA-CBER-2022-1614-3766108

	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 JAN 2020
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	15 JAN 2021
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 ■

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Data signed: (b) (4) **02 Apr 2021 14:26:24**
Generated On: 10 Jun 2021 10:07:51

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

FDA-CBER-2022-1614-3766110

	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)*	08 OCT 2020
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	08 OCT 2020
Was this medication taken for solicited event?	Yes ■
	No ☐
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Data signed: (b) (4) **02 Apr 2021 14:26:24**
Generated On: 10 Jun 2021 10:07:51

Name of Medication	FLUZONE HIGH DOSE FLU VACCINE
Prophylaxis	Yes ■ No ☐
Indication	PROPHYLAXIS FOR INFLUENZA
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)*	14 AUG 2020
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	14 AUG 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 ☐

US3862141
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures Summary
Data signed: (b) (4) **02 Apr 2021 14:26:25**
Generated On: 10 Jun 2021 10:07:51

Were any concomitant procedures performed?	Yes ☐
	No ■

If yes, please complete Concomitant Procedures form.

FDA-CBER-2022-1614-3766114

US3862141
Folder: End of Study (1)
Form: Dosing Discontinuation
Generated On: 10 Jun 2021 10:07:51

Date of dosing discontinuation (dd MMM yyyy)	
Primary reason for dosing discontinuation	AE (specify) ☐ SAE (specify) ☐ Death ☐ Lost To Follow-up ☐ Physician decision (specify) ☐ Pregnancy ☐ Protocol deviation (specify) ☐ Study Terminated By Sponsor ☐ Withdrawal of consent by participant (specify) ☐ Due to SARS-COV-2 ☐ Other ☐
If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify	

FDA-CBER-2022-1614-3766115

US3862141
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Data signed: (b) (4) **23 Apr 2021 14:01:28**
Generated On: 10 Jun 2021 10:07:51

Date of study discontinuation/completion *(dd MMM yyyy)*	09 MAR 2021
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)*	09 MAR 2021
Was autopsy performed?	Yes ☐ No ☐ Unknown ■

FDA-CBER-2022-1614-3766116

US3862141
Folder: SAE USA-US121-2021-MRNA-1273-P301000004
Form: Safety Report Form
Data signed: (b) (4) **02 Apr 2021 14:26:25**
Generated On: 10 Jun 2021 10:07:51

SAEID	USA-US121-2021-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	THEA MARIE
Investigator's Last Name	CORDERO
Site Address: Street	ONE BAYLOR PLAZA, MS 280, ROOM 221D
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77030
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

FDA-CBER-2022-1614-3766117

US3862141
Folder: SAE USA-US121-2021-MRNA-1273-P301000004
Form: Safety Report Form (1)
Data signed: (b) (4) **02 Apr 2021 14:26:25**
Generated On: 10 Jun 2021 10:07:51

SAEID	USA-US121-2021-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	THEA MARIE
Investigator's Last Name	CORDERO
Site Address: Street	ONE BAYLOR PLAZA, MS 280, ROOM 221D
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77030
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	10/MAR/2021 10:11
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

US3862141
Folder: SAE USA-US121-2021-MRNA-1273-P301000004
Form: Safety Report Form (2)
Data signed: (b) (4) **02 Apr 2021 14:26:25**
Generated On: 10 Jun 2021 10:07:51

SAEID	USA-US121-2021-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	THEA MARIE
Investigator's Last Name	CORDERO
Site Address: Street	ONE BAYLOR PLAZA, MS 280, ROOM 221D
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77030
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	18/MAR/2021 07:32
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3862141
Folder: SAE USA-US121-2021-MRNA-1273-P301000004
Form: Safety Report Form (3)
Data signed: (b) (4) **02 Apr 2021 14:26:25**
Generated On: 10 Jun 2021 10:07:51

SAEID	USA-US121-2021-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	THEA MARIE
Investigator's Last Name	CORDERO
Site Address: Street	ONE BAYLOR PLAZA, MS 280, ROOM 221D
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77030
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	22/MAR/2021 13:27
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.	True

FDA-CBER-2022-1614-3766120

Audit

US3862141 (Prod: Baylor College of Medicine)

US3862141
Form: Participant Creation
Generated On: 10 Jun 2021 10:07:51
Participant ID

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'US3862141'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	08 Sep 2020 16:39:57

FDA-CBER-2022-1614-3766122

US3862141
Folder: Screening
Form: Visit Date
Generated On: 10 Jun 2021 10:07:51
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered 'Yes (Y)'	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 17:53:28

FDA-CBER-2022-1614-3766123

US3862141
Folder: Screening
Form: Visit Date
Generated On: 10 Jun 2021 10:07:51
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered '08 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	08 Sep 2020 16:39:58

FDA-CBER-2022-1614-3766124

US3862141
Folder: Screening
Form: Visit Date
Generated On: 10 Jun 2021 10:07:51
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered 'Clinic (Clinic)'	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 17:53:28

US3862141
Folder: Screening
Form: Visit Date
Generated On: 10 Jun 2021 10:07:51
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User entered 'SCRN'	System	08 Sep 2020 17:53:28

FDA-CBER-2022-1614-3766126

US3862141
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 10:07:51
Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered (b) (6) 1947'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	08 Sep 2020 16:39:59

FDA-CBER-2022-1614-3766127

US3862141
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 10:07:51
Age

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User closed query 'Age does not fit Cohort. Please review and update.' (Site from System).	System	14 Sep 2020 15:04:26
User closed query 'Age does not fit Date of Birth.' (Site from System).	System	14 Sep 2020 15:04:26
User entered '72' reason for change: Data Entry Error	Trent Davis (b) (4) (b) (4)	14 Sep 2020 15:04:26
User opened query 'Age does not fit Cohort. Please review and update.' (Site from System).	System	08 Sep 2020 19:23:02
User opened query 'Age does not fit Date of Birth.' (Site from System).	System	08 Sep 2020 19:23:02
User entered '42'	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:23:02

US3862141
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 10:07:51
Age Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User entered 'YEARS'	System	08 Sep 2020 19:23:02

FDA-CBER-2022-1614-3766129

US3862141
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 10:07:51
Age (Derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User entered '72'	System	08 Sep 2020 17:53:50

FDA-CBER-2022-1614-3766130

US3862141
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 10:07:51
Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User closed query 'Per CDM: Sex is mentioned as Male. Childbearing potential page is not required for the participant Male, that page should be made blank and inactivated. Kindly verify make the corrections for this page. Else clarify.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 13:55:04
Query 'Per CDM: Sex is mentioned as Male. Childbearing potential page is not required for the participant Male, that page should be made blank and inactivated. Kindly verify make the corrections for this page. Else clarify.' answered with 'Data Corrected ' (Site from DM).	Shetel Anassi (b) (4) (b) (4)	20 Oct 2020 18:16:20
User opened query 'Per CDM: Sex is mentioned as Male. Childbearing potential page is not required for the participant Male, that page should be made blank and inactivated. Kindly verify make the corrections for this page. Else clarify.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 08:56:53
User entered 'Male (M)' reason for change: Data Entry Error	Carrie Kibler (b) (4) (b) (4)	06 Oct 2020 17:23:19
User entered 'Female (F)'	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:23:02

US3862141
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 10:07:51
Ethnicity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)' reason for change: Data Entry Error	Carrie Kibler (b) (4) (b) (4)	06 Oct 2020 17:23:19
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:23:02

US3862141
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 10:07:51
White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered '0' reason for change: Data Entry Error	Carrie Kibler (b) (4) (b) (4)	06 Oct 2020 17:23:19
User entered '1'	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:23:02

FDA-CBER-2022-1614-3766133

US3862141
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 10:07:51
Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered '0'	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:23:02

FDA-CBER-2022-1614-3766134

US3862141
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 10:07:51
Asian

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered '1' reason for change: Data Entry Error	Carrie Kibler (b) (4) (b) (4)	06 Oct 2020 17:23:19
User entered '0'	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:23:02

US3862141
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 10:07:51
American Indian or Alaska Native

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered '0'	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:23:02

US3862141
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 10:07:51
Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered '0'	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:23:02

US3862141
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 10:07:51
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered '0'	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:23:02

US3862141
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 10:07:51
If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered empty.	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:23:02

US3862141
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 10:07:51
Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered '0'	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:23:02

US3862141
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 10:07:51
Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered '0'	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:23:02

US3862141
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 10:07:51
Date of Informed Consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered '08 Sep 2020'	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 17:53:50

FDA-CBER-2022-1614-3766142

US3862141
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 10:07:51
Month and Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User entered 'Sep 2020'	System	08 Sep 2020 17:53:50

FDA-CBER-2022-1614-3766143

US3862141
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 10:07:51
Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User entered '2020'	System	08 Sep 2020 17:53:50

FDA-CBER-2022-1614-3766144

US3862141
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 10:07:51
Protocol Version

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered 'Amendment 3 (3)'	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 17:53:50

FDA-CBER-2022-1614-3766145

US3862141
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 10:07:51
Was participant enrolled in the study?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered 'Yes (Y)'	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 17:53:50

FDA-CBER-2022-1614-3766146

US3862141
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 10:07:51
If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered empty.	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 17:53:50

FDA-CBER-2022-1614-3766147

US3862141
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 10:07:51
If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered empty.	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 17:53:50

FDA-CBER-2022-1614-3766148

US3862141
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 10:07:51
Was this participant screened previously?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered 'No (N)'	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 17:53:50

FDA-CBER-2022-1614-3766149

US3862141
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 10:07:51
If Yes, previous participant number

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	08 Sep 2020 16:39:58

US3862141
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 10:07:51
Enrollment Trigger

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User entered '1'	System	08 Sep 2020 17:54:56

FDA-CBER-2022-1614-3766151

US3862141
Folder: Screening
Form: Inclusion/Exclusion Criteria Summary
Generated On: 10 Jun 2021 10:07:51
Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered 'Yes (Y)'	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 17:54:56

FDA-CBER-2022-1614-3766152

US3862141
Folder: Screening
Form: Medical History Summary
Generated On: 10 Jun 2021 10:07:51
Were any significant conditions reported?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered 'Yes (Y)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:23:54

US3862141
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 10:07:51
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 14:25:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 14:25:47
Data point term sent to Coder	System	14 Sep 2020 14:24:43
User entered 'Seasonal Allergies'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:24:19

US3862141
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 10:07:51
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered 'un UNK 2010'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:24:19

US3862141
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 10:07:51
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered '0'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:24:19

US3862141
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 10:07:51
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered 'Yes (Y)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:24:19

US3862141
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 10:07:51
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered empty.	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:24:19

US3862141
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 10:07:51
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered '0'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:24:19

US3862141
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 10:07:51
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User entered 'Jan 2010'	System	14 Sep 2020 14:24:19

FDA-CBER-2022-1614-3766160

US3862141
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 10:07:51
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User entered '2010'	System	14 Sep 2020 14:24:19

FDA-CBER-2022-1614-3766161

US3862141
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 10:07:51
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User entered empty.	System	14 Sep 2020 14:24:19

FDA-CBER-2022-1614-3766162

US3862141
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 10:07:51
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User entered empty.	System	14 Sep 2020 14:24:19

FDA-CBER-2022-1614-3766163

US3862141
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 10:07:51
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User coded data point as SOC: Cardiac disorders, HLGT: Heart failures, HLT: Heart failures NEC, PT: Cardiac failure congestive, LLT: Congestive heart failure - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 14:26:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 14:26:44
Data point term sent to Coder	System	14 Sep 2020 14:25:43
User entered 'Congestive heart failure'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:25:29

US3862141
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 10:07:51
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered 'un UNK 2004'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:25:29

US3862141
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 10:07:51
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered '0'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:25:29

US3862141
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 10:07:51
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered 'Yes (Y)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:25:29

US3862141
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 10:07:51
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered empty.	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:25:29

FDA-CBER-2022-1614-3766168

US3862141
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 10:07:51
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered '0'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:25:29

US3862141
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 10:07:51
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User entered 'Jan 2004'	System	14 Sep 2020 14:25:29

FDA-CBER-2022-1614-3766170

US3862141
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 10:07:51
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User entered '2004'	System	14 Sep 2020 14:25:29

US3862141
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 10:07:51
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User entered empty.	System	14 Sep 2020 14:25:29

FDA-CBER-2022-1614-3766172

US3862141
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 10:07:51
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User entered empty.	System	14 Sep 2020 14:25:29

FDA-CBER-2022-1614-3766173

US3862141
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 10:07:51
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery disease, LLT: Coronary artery disease - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 14:27:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 14:27:48
Data point term sent to Coder	System	14 Sep 2020 14:26:44
User entered 'Coronary Artery Disease'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:25:47

US3862141
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 10:07:51
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered 'un UNK 2005'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:25:47

US3862141
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 10:07:51
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered '0'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:25:47

US3862141
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 10:07:51
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered 'Yes (Y)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:25:47

FDA-CBER-2022-1614-3766177

US3862141
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 10:07:51
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered empty.	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:25:47

FDA-CBER-2022-1614-3766178

US3862141
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 10:07:51
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered '0'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:25:47

US3862141
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 10:07:51
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User entered 'Jan 2005'	System	14 Sep 2020 14:25:47

FDA-CBER-2022-1614-3766180

US3862141
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 10:07:51
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User entered '2005'	System	14 Sep 2020 14:25:47

FDA-CBER-2022-1614-3766181

US3862141
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 10:07:51
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User entered empty.	System	14 Sep 2020 14:25:47

FDA-CBER-2022-1614-3766182

US3862141
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 10:07:51
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User entered empty.	System	14 Sep 2020 14:25:47

FDA-CBER-2022-1614-3766183

US3862141
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 10:07:51
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type 2 diabetes mellitus - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 14:27:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 14:27:48
Data point term sent to Coder	System	14 Sep 2020 14:26:45
User entered 'diabetes mellitus type 2'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:26:26

US3862141
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 10:07:51
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered 'un UNK 1990'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:26:26

US3862141
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 10:07:51
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered '0'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:26:26

US3862141
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 10:07:51
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered 'Yes (Y)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:26:26

US3862141
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 10:07:51
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered empty.	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:26:26

FDA-CBER-2022-1614-3766188

US3862141
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 10:07:51
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered '0'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:26:26

US3862141
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 10:07:51
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User entered 'Jan 1990'	System	14 Sep 2020 14:26:26

FDA-CBER-2022-1614-3766190

US3862141
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 10:07:51
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User entered '1990'	System	14 Sep 2020 14:26:26

US3862141
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 10:07:51
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User entered empty.	System	14 Sep 2020 14:26:26

FDA-CBER-2022-1614-3766192

US3862141
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 10:07:51
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User entered empty.	System	14 Sep 2020 14:26:26

FDA-CBER-2022-1614-3766193

US3862141
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 10:07:51
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:49:55
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) (4), (b) (6)	04 Nov 2020 09:44:34
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 'Subject reported monitoring HTN with exercise and diet. ' (Site from DM).	Shetel Anassi (b) (4) (b) (4)	29 Oct 2020 19:13:07
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)	13 Oct 2020 06:28:33
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 14:28:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 14:28:51
Data point term sent to Coder	System	14 Sep 2020 14:27:45
User entered 'Hypertension'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:27:24

FDA-CBER-2022-1614-3766194

US3862141
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 10:07:51
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered 'un UNK 2004'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:27:24

US3862141
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 10:07:51
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered '0'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:27:24

US3862141
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 10:07:51
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered 'Yes (Y)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:27:24

US3862141
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 10:07:51
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered empty.	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:27:24

FDA-CBER-2022-1614-3766198

US3862141
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 10:07:51
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered '0'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:27:24

US3862141
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 10:07:51
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User entered 'Jan 2004'	System	14 Sep 2020 14:27:24

FDA-CBER-2022-1614-3766200

US3862141
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 10:07:51
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User entered '2004'	System	14 Sep 2020 14:27:24

FDA-CBER-2022-1614-3766201

US3862141
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 10:07:51
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User entered empty.	System	14 Sep 2020 14:27:24

US3862141
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 10:07:51
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User entered empty.	System	14 Sep 2020 14:27:24

FDA-CBER-2022-1614-3766203

US3862141
Folder: Screening
Form: Medical History (6)
Generated On: 10 Jun 2021 10:07:51
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Purine and pyrimidine metabolism disorders, HLT: Disorders of purine metabolism, PT: Gout, LLT: Gout - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 00:31:32
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 00:31:32
User closed query 'Per DM CLR: Please update the condition to include the type and/or location of GOUT (arms, Legs,). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 12:03:07
Query 'Per DM CLR: Please update the condition to include the type and/or location of GOUT (arms, Legs,). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'data entered' (Site from DM).	Trent Davis (b) (4) (b) (4)	03 Nov 2020 20:51:20
Data point term sent to Coder	System	03 Nov 2020 20:46:47
Coding entries removed.	Trent Davis (b) (4) (b) (4)	03 Nov 2020 20:46:14
User entered 'GOUT of both feet' reason for change: Data Entry Error	Trent Davis (b) (4) (b) (4)	03 Nov 2020 20:46:14
User opened query 'Per DM CLR: Please update the condition to include the type and/or location of GOUT (arms, Legs,). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 06:27:49
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Purine and pyrimidine metabolism disorders, HLT: Disorders of purine metabolism, PT: Gout, LLT: Gout - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 14:29:14

US3862141
Folder: Screening
Form: Medical History (6)
Generated On: 10 Jun 2021 10:07:51
Condition

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 14:29:14
Data point term sent to Coder	System	14 Sep 2020 14:27:48
User entered 'Gout'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:27:38

US3862141
Folder: Screening
Form: Medical History (6)
Generated On: 10 Jun 2021 10:07:51
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered 'un UNK 2016'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:27:38

US3862141
Folder: Screening
Form: Medical History (6)
Generated On: 10 Jun 2021 10:07:51
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered '0'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:27:38

US3862141
Folder: Screening
Form: Medical History (6)
Generated On: 10 Jun 2021 10:07:51
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered 'Yes (Y)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:27:38

US3862141
Folder: Screening
Form: Medical History (6)
Generated On: 10 Jun 2021 10:07:51
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered empty.	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:27:38

FDA-CBER-2022-1614-3766209

US3862141
Folder: Screening
Form: Medical History (6)
Generated On: 10 Jun 2021 10:07:51
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered '0'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:27:38

US3862141
Folder: Screening
Form: Medical History (6)
Generated On: 10 Jun 2021 10:07:51
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User entered 'Jan 2016'	System	14 Sep 2020 14:27:38

FDA-CBER-2022-1614-3766211

US3862141
Folder: Screening
Form: Medical History (6)
Generated On: 10 Jun 2021 10:07:51
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User entered '2016'	System	14 Sep 2020 14:27:38

FDA-CBER-2022-1614-3766212

US3862141
Folder: Screening
Form: Medical History (6)
Generated On: 10 Jun 2021 10:07:51
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User entered empty.	System	14 Sep 2020 14:27:38

FDA-CBER-2022-1614-3766213

US3862141
Folder: Screening
Form: Medical History (6)
Generated On: 10 Jun 2021 10:07:51
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User entered empty.	System	14 Sep 2020 14:27:38

FDA-CBER-2022-1614-3766214

US3862141
Folder: Screening
Form: Medical History (7)
Generated On: 10 Jun 2021 10:07:51
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:49:55
User closed query 'Please confirm what this condition is and correct spelling.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:56:58
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal ulceration and perforation, HLT: Peptic ulcers and perforation, PT: Peptic ulcer, LLT: Peptic ulcer - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Sep 2020 18:50:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Sep 2020 18:50:45
Data point term sent to Coder	System	22 Sep 2020 18:49:37
Query 'Please confirm what this condition is and correct spelling.' answered with 'Corrected spelling' (Site from CRA).	Carrie Kibler (b) (4) (b) (4)	22 Sep 2020 18:48:57
User entered 'PEPTIC ULCER' reason for change: Data Entry Error	Carrie Kibler (b) (4) (b) (4)	22 Sep 2020 18:48:42
User opened query 'Please confirm what this condition is and correct spelling.' (Site from CRA).	(b) (4), (b) (6)	21 Sep 2020 23:50:45
Data point term sent to Coder	System	14 Sep 2020 14:40:02
User entered 'Pepeticular'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:39:45

US3862141
Folder: Screening
Form: Medical History (7)
Generated On: 10 Jun 2021 10:07:51
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered 'un UNK 2016'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:39:45

US3862141
Folder: Screening
Form: Medical History (7)
Generated On: 10 Jun 2021 10:07:51
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered '0'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:39:45

US3862141
Folder: Screening
Form: Medical History (7)
Generated On: 10 Jun 2021 10:07:51
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered 'Yes (Y)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:39:45

US3862141
Folder: Screening
Form: Medical History (7)
Generated On: 10 Jun 2021 10:07:51
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered empty.	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:39:45

FDA-CBER-2022-1614-3766219

US3862141
Folder: Screening
Form: Medical History (7)
Generated On: 10 Jun 2021 10:07:51
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered '0'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:39:45

US3862141
Folder: Screening
Form: Medical History (7)
Generated On: 10 Jun 2021 10:07:51
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User entered 'Jan 2016'	System	14 Sep 2020 14:39:45

FDA-CBER-2022-1614-3766221

US3862141
Folder: Screening
Form: Medical History (7)
Generated On: 10 Jun 2021 10:07:51
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User entered '2016'	System	14 Sep 2020 14:39:45

FDA-CBER-2022-1614-3766222

US3862141
Folder: Screening
Form: Medical History (7)
Generated On: 10 Jun 2021 10:07:51
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User entered empty.	System	14 Sep 2020 14:39:45

FDA-CBER-2022-1614-3766223

US3862141
Folder: Screening
Form: Medical History (7)
Generated On: 10 Jun 2021 10:07:51
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User entered empty.	System	14 Sep 2020 14:39:45

FDA-CBER-2022-1614-3766224

US3862141
Folder: Screening
Form: Medical History (8)
Generated On: 10 Jun 2021 10:07:51
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User coded data point as SOC: Psychiatric disorders, HLGT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 14:41:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 14:41:51
Data point term sent to Coder	System	14 Sep 2020 14:41:05
User entered 'Insomnia'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:40:15

US3862141
Folder: Screening
Form: Medical History (8)
Generated On: 10 Jun 2021 10:07:51
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered 'un UNK 2008'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:40:15

US3862141
Folder: Screening
Form: Medical History (8)
Generated On: 10 Jun 2021 10:07:51
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered '0'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:40:15

US3862141
Folder: Screening
Form: Medical History (8)
Generated On: 10 Jun 2021 10:07:51
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered 'Yes (Y)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:40:15

US3862141
Folder: Screening
Form: Medical History (8)
Generated On: 10 Jun 2021 10:07:51
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered empty.	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:40:15

US3862141
Folder: Screening
Form: Medical History (8)
Generated On: 10 Jun 2021 10:07:51
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered '0'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:40:15

US3862141
Folder: Screening
Form: Medical History (8)
Generated On: 10 Jun 2021 10:07:51
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User entered 'Jan 2008'	System	14 Sep 2020 14:40:15

FDA-CBER-2022-1614-3766231

US3862141
Folder: Screening
Form: Medical History (8)
Generated On: 10 Jun 2021 10:07:51
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User entered '2008'	System	14 Sep 2020 14:40:15

FDA-CBER-2022-1614-3766232

US3862141
Folder: Screening
Form: Medical History (8)
Generated On: 10 Jun 2021 10:07:51
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User entered empty.	System	14 Sep 2020 14:40:15

US3862141
Folder: Screening
Form: Medical History (8)
Generated On: 10 Jun 2021 10:07:51
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User entered empty.	System	14 Sep 2020 14:40:15

US3862141
Folder: Screening
Form: Medical History (9)
Generated On: 10 Jun 2021 10:07:51
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
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)	14 Sep 2020 14:42:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 14:42:47
Data point term sent to Coder	System	14 Sep 2020 14:42:08
User entered 'Atrial Fibrillation'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:41:37

US3862141
Folder: Screening
Form: Medical History (9)
Generated On: 10 Jun 2021 10:07:51
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered 'un UNK 2004'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:41:37

US3862141
Folder: Screening
Form: Medical History (9)
Generated On: 10 Jun 2021 10:07:51
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered '0'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:41:37

US3862141
Folder: Screening
Form: Medical History (9)
Generated On: 10 Jun 2021 10:07:51
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered 'Yes (Y)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:41:37

US3862141
Folder: Screening
Form: Medical History (9)
Generated On: 10 Jun 2021 10:07:51
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered empty.	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:41:37

FDA-CBER-2022-1614-3766239

US3862141
Folder: Screening
Form: Medical History (9)
Generated On: 10 Jun 2021 10:07:51
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered '0'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:41:37

US3862141
Folder: Screening
Form: Medical History (9)
Generated On: 10 Jun 2021 10:07:51
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User entered 'Jan 2004'	System	14 Sep 2020 14:41:37

US3862141
Folder: Screening
Form: Medical History (9)
Generated On: 10 Jun 2021 10:07:51
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User entered '2004'	System	14 Sep 2020 14:41:37

FDA-CBER-2022-1614-3766242

US3862141
Folder: Screening
Form: Medical History (9)
Generated On: 10 Jun 2021 10:07:51
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User entered empty.	System	14 Sep 2020 14:41:37

FDA-CBER-2022-1614-3766243

US3862141
Folder: Screening
Form: Medical History (9)
Generated On: 10 Jun 2021 10:07:51
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User entered empty.	System	14 Sep 2020 14:41:37

FDA-CBER-2022-1614-3766244

US3862141
Folder: Screening
Form: Medical History (10)
Generated On: 10 Jun 2021 10:07:51
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 14:42:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 14:42:46
Data point term sent to Coder	System	14 Sep 2020 14:42:07
User entered 'Hypothyroidism'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:41:59

US3862141
Folder: Screening
Form: Medical History (10)
Generated On: 10 Jun 2021 10:07:51
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered 'un UNK 1995'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:41:59

US3862141
Folder: Screening
Form: Medical History (10)
Generated On: 10 Jun 2021 10:07:51
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered '0'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:41:59

US3862141
Folder: Screening
Form: Medical History (10)
Generated On: 10 Jun 2021 10:07:51
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered 'Yes (Y)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:41:59

US3862141
Folder: Screening
Form: Medical History (10)
Generated On: 10 Jun 2021 10:07:51
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered empty.	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:41:59

US3862141
Folder: Screening
Form: Medical History (10)
Generated On: 10 Jun 2021 10:07:51
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered '0'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:41:59

US3862141
Folder: Screening
Form: Medical History (10)
Generated On: 10 Jun 2021 10:07:51
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User entered 'Jan 1995'	System	14 Sep 2020 14:41:59

FDA-CBER-2022-1614-3766251

US3862141
Folder: Screening
Form: Medical History (10)
Generated On: 10 Jun 2021 10:07:51
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User entered '1995'	System	14 Sep 2020 14:41:59

US3862141
Folder: Screening
Form: Medical History (10)
Generated On: 10 Jun 2021 10:07:51
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User entered empty.	System	14 Sep 2020 14:41:59

FDA-CBER-2022-1614-3766253

US3862141
Folder: Screening
Form: Medical History (10)
Generated On: 10 Jun 2021 10:07:51
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User entered empty.	System	14 Sep 2020 14:41:59

FDA-CBER-2022-1614-3766254

US3862141
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 10:07:51
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered 'Yes (Y)'	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:21:43

US3862141
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 10:07:51
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered '08 Sep 2020'	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:21:43

US3862141
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 10:07:51
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered '11:51'	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:21:43

FDA-CBER-2022-1614-3766257

US3862141
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 10:07:51
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User entered '08 Sep 2020 11:51'	System	08 Sep 2020 19:21:43

US3862141
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 10:07:51
Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:49:55
User entered '159' cm	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:21:43
DataPoint set to visible.	System	08 Sep 2020 17:54:56

US3862141
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 10:07:51
Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:49:55
User entered '185.5' lb	(b) (4) Sandra Francisco (b) (4)	08 Sep 2020 19:21:43
DataPoint set to visible.	(b) (4) System	08 Sep 2020 17:54:56

US3862141
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 10:07:51
BMI *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User entered '33.35239'	System	08 Sep 2020 19:21:43
DataPoint set to visible.	System	08 Sep 2020 17:54:56

US3862141
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 10:07:51
BMI units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User entered 'kg/m2'	System	08 Sep 2020 19:21:43
DataPoint set to visible.	System	08 Sep 2020 17:54:56

US3862141
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 10:07:51
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:49:55
User closed query 'Please only enter height/weight info at Screening when visit is combined with Baseline, per eCRF Completion Guidelines. All vital signs will only be entered under Baseline.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:55:15
Query 'Please only enter height/weight info at Screening when visit is combined with Baseline, per eCRF Completion Guidelines. All vital signs will only be entered under Baseline.' answered with 'data entered' (Site from CRA).	Trent Davis (b) (4) (b) (4)	20 Oct 2020 16:48:32
User entered missing code ND - Not Done; reason for change Data Entry Error	Trent Davis (b) (4) (b) (4)	20 Oct 2020 16:44:47
User opened query 'Please only enter height/weight info at Screening when visit is combined with Baseline, per eCRF Completion Guidelines. All vital signs will only be entered under Baseline.' (Site from CRA).	(b) (4), (b) (6)	21 Sep 2020 23:56:59
User entered '98.6' F	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:21:43

US3862141
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 10:07:51
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered empty; reason for change Data Entry Error	Trent Davis (b) (4) (b) (4)	20 Oct 2020 16:44:47
User entered 'Oral (Oral)'	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:21:43

US3862141
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 10:07:51
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered empty.	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:21:43

US3862141
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 10:07:51
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered missing code ND - Not Done; reason for change Data Entry Error	Trent Davis (b) (4) (b) (4)	20 Oct 2020 16:44:47
User entered '60'	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:21:43

US3862141
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 10:07:51
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User entered 'bpm'	System	08 Sep 2020 19:21:43

FDA-CBER-2022-1614-3766267

US3862141
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 10:07:51
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered missing code ND - Not Done; reason for change Data Entry Error	Trent Davis (b) (4) (b) (4)	20 Oct 2020 16:44:47
User entered '16'	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:21:43

US3862141
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 10:07:51
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User entered 'breaths/min'	System	08 Sep 2020 19:21:43

FDA-CBER-2022-1614-3766269

US3862141
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 10:07:51
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered missing code ND - Not Done; reason for change Data Entry Error	Trent Davis (b) (4) (b) (4)	20 Oct 2020 16:44:47
User entered '108'	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:21:43

US3862141
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 10:07:51
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User entered 'mmHg'	System	08 Sep 2020 19:21:43

FDA-CBER-2022-1614-3766271

US3862141
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 10:07:51
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered missing code ND - Not Done; reason for change Data Entry Error	Trent Davis (b) (4) (b) (4)	20 Oct 2020 16:44:47
User entered '68'	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:21:43

US3862141
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 10:07:51
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User entered 'mmHg'	System	08 Sep 2020 19:21:43

FDA-CBER-2022-1614-3766273

US3862141
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 10:07:51
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15

FDA-CBER-2022-1614-3766274

US3862141
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 10:07:51
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15

FDA-CBER-2022-1614-3766275

US3862141
Folder: Screening
Form: Physical Examination
Generated On: 10 Jun 2021 10:07:51
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered 'Yes (Y)'	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:21:51

FDA-CBER-2022-1614-3766276

US3862141
Folder: Screening
Form: Physical Examination
Generated On: 10 Jun 2021 10:07:51
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered '8 Sep 2020'	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:21:51

US3862141
Folder: Screening
Form: Pregnancy Test
Generated On: 10 Jun 2021 10:07:51
Was the pregnancy test performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:49:55
User closed query 'Please confirm why pregnancy test would be completed on a 72 year old female.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:54:57
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	22 Oct 2020 13:52:24
Query 'Data is required. Please complete.' answered with 'Data Corrected ' (Site from System).	Shetel Anassi (b) (4) (b) (4)	20 Oct 2020 18:18:40
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 18:18:33
User entered empty; reason for change Data Entry Error	Shetel Anassi (b) (4) (b) (4)	20 Oct 2020 18:18:33
Query 'Please confirm why pregnancy test would be completed on a 72 year old female.' answered with 'Data Corrected ' (Site from CRA).	Shetel Anassi (b) (4) (b) (4)	20 Oct 2020 18:18:13
User entered 'No (N)' reason for change: Data Entry Error	Shetel Anassi (b) (4) (b) (4)	20 Oct 2020 18:15:47
User opened query 'Please confirm why pregnancy test would be completed on a 72 year old female.' (Site from CRA).	(b) (4), (b) (6)	21 Sep 2020 23:59:34
User entered 'Yes (Y)'	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:24:00

US3862141
Folder: Screening
Form: Pregnancy Test
Generated On: 10 Jun 2021 10:07:51
Date of test *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered empty; reason for change Data Entry Error	Shetel Anassi (b) (4) (b) (4)	20 Oct 2020 18:15:47
User entered '08 Sep 2020'	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:24:00

US3862141
Folder: Screening
Form: Pregnancy Test
Generated On: 10 Jun 2021 10:07:51
Test performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered empty; reason for change Data Entry Error	Shetel Anassi (b) (4) (b) (4)	20 Oct 2020 18:15:47
User entered 'Urine (URINE)'	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:24:00

US3862141
Folder: Screening
Form: Pregnancy Test
Generated On: 10 Jun 2021 10:07:51
Result

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered empty; reason for change Data Entry Error	Shetel Anassi (b) (4) (b) (4)	20 Oct 2020 18:15:47
User entered 'Negative (NEGATIVE)'	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:24:00

US3862141
Folder: Screening
Form: Pregnancy Test
Generated On: 10 Jun 2021 10:07:51
Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered empty; reason for change Data Entry Error	Shetel Anassi (b) (4) (b) (4)	20 Oct 2020 18:18:33
User entered 'No (N)'	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:24:00

US3862141
Folder: Screening
Form: Pregnancy Test
Generated On: 10 Jun 2021 10:07:51
Collection date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:49:55
User closed query 'Please confirm - if no sample was collected, there should be no collection date/time entered.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:55:00
Query 'Please confirm - if no sample was collected, there should be no collection date/time entered.' answered with 'Data Corrected ' (Site from CRA).	Shetel Anassi (b) (4) (b) (4)	20 Oct 2020 18:18:44
User entered empty; reason for change Data Entry Error	Shetel Anassi (b) (4) (b) (4)	20 Oct 2020 18:15:47
User opened query 'Please confirm - if no sample was collected, there should be no collection date/time entered.' (Site from CRA).	(b) (4), (b) (6)	21 Sep 2020 23:59:08
User entered '08 Sep 2020'	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:24:00

US3862141
Folder: Screening
Form: Pregnancy Test
Generated On: 10 Jun 2021 10:07:51
Collection time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered empty; reason for change Data Entry Error	Shetel Anassi (b) (4) (b) (4)	20 Oct 2020 18:15:47
User entered '12:50'	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:24:00

US3862141
Folder: Screening
Form: Pregnancy Test
Generated On: 10 Jun 2021 10:07:51
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User entered empty.	System	20 Oct 2020 18:15:47
User entered '08 Sep 2020 12:50'	System	08 Sep 2020 19:24:00

US3862141
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 10:07:51
Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered 'No (N)'	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:22:40

US3862141
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 10:07:51
Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered 'No (N)'	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:22:40

US3862141
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 10:07:51
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)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered 'No (N)'	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:22:40

US3862141
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 10:07:51
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)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered 'No (N)'	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:22:40

US3862141
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 10:07:51
Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered 'No (N)'	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:22:40

US3862141
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 10:07:51
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)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered 'No (N)'	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:22:40

US3862141
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 10:07:51
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)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered 'No (N)'	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:22:40

US3862141
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 10:07:51
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)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered 'No (N)'	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:22:40

US3862141
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 10:07:51
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)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered 'No (N)'	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:22:40

US3862141
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 10:07:51
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)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered 'No (N)'	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:22:40

US3862141
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 10:07:51
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)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered 'No (N)'	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:22:40

US3862141
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 10:07:51
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered 'No (N)'	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:22:40

US3862141
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 10:07:51
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:49:55
User entered empty.	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:22:40

FDA-CBER-2022-1614-3766298

US3862141
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 10:07:51
No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered '0'	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:22:40

FDA-CBER-2022-1614-3766299

US3862141
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 10:07:51
Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered '0'	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:22:40

US3862141
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 10:07:51
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)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered '0'	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:22:40

US3862141
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 10:07:51
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)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered '0'	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:22:40

US3862141
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 10:07:51
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)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered '0'	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:22:40

US3862141
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 10:07:51
Resides in a single family home (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered '1'	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:22:40

FDA-CBER-2022-1614-3766304

US3862141
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 10:07:51
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:49:55
User entered '0'	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:22:40

US3862141
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 10:07:51
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:15
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered empty.	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:22:40

US3862141
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 10 Jun 2021 10:07:51
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered 'Yes (Y)'	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 17:56:03

FDA-CBER-2022-1614-3766307

US3862141
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 10 Jun 2021 10:07:51
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered '08 Sep 2020'	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 17:56:03

FDA-CBER-2022-1614-3766308

US3862141
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 10 Jun 2021 10:07:51
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered 'Clinic (Clinic)'	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 17:56:03

US3862141
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 10 Jun 2021 10:07:51
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User entered 'VISIT1'	System	08 Sep 2020 17:56:03

FDA-CBER-2022-1614-3766310

US3862141
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 10:07:51
What was the date of randomization? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered '08 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	08 Sep 2020 17:29:29

FDA-CBER-2022-1614-3766311

US3862141
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 10:07:51
What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered '190076'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	08 Sep 2020 17:29:29

US3862141
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 10:07:51
In what Cohort was the participant enrolled?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	08 Sep 2020 17:29:29

FDA-CBER-2022-1614-3766313

US3862141
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 10:07:51
Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered 'No (N)'	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:24:26

FDA-CBER-2022-1614-3766314

US3862141
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 10:07:51

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered 'No (N)'	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:24:26

US3862141
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 10:07:51
Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered 'No (N)'	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:24:26

US3862141
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 10:07:51
Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered 'No (N)'	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:24:26

US3862141
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 10:07:51
Liver Disease

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered 'No (N)'	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:24:26

US3862141
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 10:07:51
Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:49:55
User entered 'No (N)'	Carrie Kibler (b) (4) (b) (4)	22 Sep 2020 18:44:34
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 05:39:38
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 05:39:37

FDA-CBER-2022-1614-3766319

US3862141
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 10:07:51
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:49:55
User closed query 'Per CDM: Subject noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update ND in the field Height and Weight and remove the units accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:11:36
Query 'Per CDM: Subject noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update ND in the field Height and Weight and remove the units accordingly. ' answered with 'Data Corrected ' (Site from DM).	Shetel Anassi (b) (4) (b) (4)	20 Oct 2020 17:07:38
User entered missing code ND - Not Done; reason for change Data Entry Error	Shetel Anassi (b) (4) (b) (4)	20 Oct 2020 17:07:35
User opened query 'Per CDM: Subject noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update ND in the field Height and Weight and remove the units accordingly. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 13:25:16
User entered '159' cm	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:27:14

US3862141
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 10:07:51
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered missing code ND - Not Done; reason for change Data Entry Error	Shetel Anassi (b) (4) (b) (4)	20 Oct 2020 17:07:35
User entered '185.5' lb	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:27:14

US3862141
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 10:07:51
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:49:55
User closed query 'Per CDM: Subject noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update ND in the field Height and Weight and remove the units accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:11:36
Query 'Per CDM: Subject noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update ND in the field Height and Weight and remove the units accordingly. ' answered with 'Data Corrected ' (Site from DM).	Shetel Anassi (b) (4) (b) (4)	20 Oct 2020 17:07:38
User entered missing code ND - Not Done; reason for change Data Entry Error	Shetel Anassi (b) (4) (b) (4)	20 Oct 2020 17:07:35
User opened query 'Per CDM: Subject noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update ND in the field Height and Weight and remove the units accordingly. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 13:25:16
User entered '159' cm	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:27:14

FDA-CBER-2022-1614-3766322

US3862141
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 10:07:51
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered missing code ND - Not Done; reason for change Data Entry Error	Shetel Anassi (b) (4) (b) (4)	20 Oct 2020 17:07:35
User entered '185.5' lb	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:27:14

US3862141
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 10:07:51
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User accepted default value 'Pre-Dose (PREDOSE)'	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:27:14

FDA-CBER-2022-1614-3766324

US3862141
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 10:07:51
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered 'Yes (Y)'	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:27:14

US3862141
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 10:07:51
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered '08 Sep 2020'	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:27:14

FDA-CBER-2022-1614-3766326

US3862141
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 10:07:51
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered '11:51'	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:27:14

US3862141
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 10:07:51
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User entered '08 Sep 2020 11:51'	System	08 Sep 2020 19:27:14

FDA-CBER-2022-1614-3766328

US3862141
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 10:07:51
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered '98.6' F	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:27:14

US3862141
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 10:07:51
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered 'Oral (Oral)'	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:27:14

FDA-CBER-2022-1614-3766330

US3862141
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 10:07:51
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered empty.	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:27:14

US3862141
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 10:07:51
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered '60'	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:27:14

FDA-CBER-2022-1614-3766332

US3862141
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 10:07:51
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User entered 'bpm'	System	08 Sep 2020 19:27:14

FDA-CBER-2022-1614-3766333

US3862141
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 10:07:51
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User closed query 'Data is required. Please provide.' (Site from System).	System	08 Sep 2020 19:27:41
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	08 Sep 2020 19:27:41
User entered '16' reason for change: Data Entry Error	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:27:41
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Sep 2020 19:27:14
User entered empty.	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:27:14

US3862141
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 10:07:51
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User entered 'breaths/min'	System	08 Sep 2020 19:27:41
User entered empty.	System	08 Sep 2020 19:27:14

US3862141
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 10:07:51
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User closed query 'Data is required. Please provide.' (Site from System).	System	08 Sep 2020 19:27:41
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	08 Sep 2020 19:27:41
User entered '108' reason for change: Data Entry Error	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:27:41
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Sep 2020 19:27:14
User entered empty.	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:27:14

FDA-CBER-2022-1614-3766336

US3862141
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 10:07:51
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User entered 'mmHg'	System	08 Sep 2020 19:27:41
User entered empty.	System	08 Sep 2020 19:27:14

US3862141
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 10:07:51
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User closed query 'Data is required. Please provide.' (Site from System).	System	08 Sep 2020 19:27:41
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	08 Sep 2020 19:27:41
User entered '68' reason for change: Data Entry Error	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:27:41
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Sep 2020 19:27:14
User entered empty.	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:27:14

FDA-CBER-2022-1614-3766338

US3862141
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 10:07:51
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User entered 'mmHg'	System	08 Sep 2020 19:27:41
User entered empty.	System	08 Sep 2020 19:27:14

US3862141
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 10:07:51
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:49:55
User closed query 'Per CDM: Subject noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update ND in the field Height and Weight and remove the units accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Oct 2020 15:11:36
Query 'Per CDM: Subject noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update ND in the field Height and Weight and remove the units accordingly. ' answered with 'Data Corrected ' (Site from DM).	Shetel Anassi (b) (4) (b) (4)	20 Oct 2020 17:07:38
User entered missing code ND - Not Done; reason for change Data Entry Error	Shetel Anassi (b) (4) (b) (4)	20 Oct 2020 17:07:35
User opened query 'Per CDM: Subject noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update ND in the field Height and Weight and remove the units accordingly. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 13:25:16
User entered '159' cm	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:27:14

US3862141
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 10:07:51
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered missing code ND - Not Done; reason for change Data Entry Error	Shetel Anassi (b) (4) (b) (4)	20 Oct 2020 17:07:35
User entered '185.5' lb	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:27:14

FDA-CBER-2022-1614-3766341

US3862141
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 10:07:51
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User accepted default value 'Post-Dose (POSTDOSE)'	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:27:14

FDA-CBER-2022-1614-3766342

US3862141
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 10:07:51
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Sep 2020 23:37:28
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Sep 2020 23:37:28
User entered 'Yes (Y)' reason for change: New Information	Chanei Henry (b) (4) (b) (4)	16 Sep 2020 23:37:28
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 19:27:14
User entered empty.	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:27:14

US3862141
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 10:07:51
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered '8 Sep 2020' reason for change: New Information	Chanei Henry (b) (4) (b) (4)	16 Sep 2020 23:37:28
User entered empty.	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:27:14

US3862141
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 10:07:51
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered '13:15' reason for change: New Information	Chanei Henry (b) (4) (b) (4)	16 Sep 2020 23:37:28
User entered empty.	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:27:14

US3862141
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 10:07:51
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User entered '8 Sep 2020 13:15'	System	16 Sep 2020 23:37:28
User entered empty.	System	08 Sep 2020 19:27:14

FDA-CBER-2022-1614-3766346

US3862141
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 10:07:51
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered '98.4' F reason for change: New Information	Chanei Henry (b) (4) (b) (4)	16 Sep 2020 23:37:28
User entered empty.	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:27:14

FDA-CBER-2022-1614-3766347

US3862141
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 10:07:51
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered 'Oral (Oral)' reason for change: New Information	Chanei Henry (b) (4) (b) (4)	16 Sep 2020 23:37:28
User entered empty.	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:27:14

US3862141
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 10:07:51
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered empty.	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:27:14

US3862141
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 10:07:51
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered '65' reason for change: New Information	Chanei Henry (b) (4) (b) (4)	16 Sep 2020 23:37:28
User entered empty.	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:27:14

FDA-CBER-2022-1614-3766350

US3862141
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 10:07:51
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User entered 'bpm'	System	16 Sep 2020 23:37:28
User entered empty.	System	08 Sep 2020 19:27:14

US3862141
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 10:07:51
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered '20' reason for change: New Information	Chanei Henry (b) (4) (b) (4)	16 Sep 2020 23:37:28
User entered empty.	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:27:14

FDA-CBER-2022-1614-3766352

US3862141
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 10:07:51
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User entered 'breaths/min'	System	16 Sep 2020 23:37:28
User entered empty.	System	08 Sep 2020 19:27:14

US3862141
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 10:07:51
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered '165' reason for change: New Information	Chanei Henry (b) (4) (b) (4)	16 Sep 2020 23:37:28
User entered empty.	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:27:14

US3862141
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 10:07:51
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User entered 'mmHg'	System	16 Sep 2020 23:37:28
User entered empty.	System	08 Sep 2020 19:27:14

US3862141
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 10:07:51
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered '80' reason for change: New Information	Chanei Henry (b) (4) (b) (4)	16 Sep 2020 23:37:28
User entered empty.	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:27:14

US3862141
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 10:07:51
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User entered 'mmHg'	System	16 Sep 2020 23:37:28
User entered empty.	System	08 Sep 2020 19:27:14

US3862141
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 10 Jun 2021 10:07:51
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User closed query 'Please remove, as PE is only entered on the Screening visit when the visit is combined with Baseline, per eCRF Completion Guidelines.' (Site from CRA).	(b) (4), (b) (6)	26 Oct 2020 16:54:39
Query 'Please remove, as PE is only entered on the Screening visit when the visit is combined with Baseline, per eCRF Completion Guidelines.' answered with 'data corrected' (Site from CRA).	Trent Davis (b) (4) (b) (4)	20 Oct 2020 17:16:34
User entered 'No (N)' reason for change: Data Entry Error	Trent Davis (b) (4) (b) (4)	20 Oct 2020 17:16:26
User opened query 'Please remove, as PE is only entered on the Screening visit when the visit is combined with Baseline, per eCRF Completion Guidelines.' (Site from CRA).	(b) (4), (b) (6)	22 Sep 2020 00:01:41
User entered 'Yes (Y)'	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:30:02

FDA-CBER-2022-1614-3766358

US3862141
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 10 Jun 2021 10:07:51
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered empty; reason for change Data Entry Error	Trent Davis (b) (4) (b) (4)	20 Oct 2020 17:16:26
User entered '8 Sep 2020'	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:30:02

US3862141
Folder: Visit 1 Day 1
Form: Pregnancy Test
Generated On: 10 Jun 2021 10:07:51
Was the pregnancy test performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:49:55
User closed query 'Please confirm why pregnancy test would be completed on a 72 year old female.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:54:26
User closed query 'Data is required. Please complete.' (Site from System).		22 Oct 2020 15:11:55
User closed query 'Per CDM: If Screening visit and Dosing are done on the same day, then Pregnancy test should only be completed at the 'Screening Visit' only and marked as "No" at V1D1 to avoid duplication. Please review and update accordingly.' (Site from DM).		22 Oct 2020 15:11:54
Query 'Please confirm why pregnancy test would be completed on a 72 year old female.' answered with 'Data Corrected ' (Site from CRA).	Shetel Anassi (b) (4) (b) (4)	20 Oct 2020 18:20:10
Query 'Per CDM: If Screening visit and Dosing are done on the same day, then Pregnancy test should only be completed at the 'Screening Visit' only and marked as "No" at V1D1 to avoid duplication. Please review and update accordingly.' answered with 'Data Corrected ' (Site from DM).	Shetel Anassi (b) (4) (b) (4)	20 Oct 2020 18:20:05
Query 'Data is required. Please complete.' answered with 'Data Corrected ' (Site from System).	Shetel Anassi (b) (4) (b) (4)	20 Oct 2020 18:19:57
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 18:19:42
User entered empty; reason for change Data Entry Error	Shetel Anassi (b) (4) (b) (4)	20 Oct 2020 18:19:42
User opened query 'Per CDM: If Screening visit and Dosing are done on the same day, then Pregnancy test should only be completed at the 'Screening Visit' only and marked as "No" at V1D1 to avoid duplication. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 12:30:16
User opened query 'Please confirm why pregnancy test would be completed on a 72 year old female.' (Site from CRA).	(b) (4), (b) (6)	22 Sep 2020 00:02:08
User entered 'Yes (Y)'	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:34:48

US3862141
Folder: Visit 1 Day 1
Form: Pregnancy Test
Generated On: 10 Jun 2021 10:07:51
Date of test *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered empty; reason for change Data Entry Error	Shetel Anassi (b) (4) (b) (4)	20 Oct 2020 18:19:42
User entered '08 Sep 2020'	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:34:48

FDA-CBER-2022-1614-3766361

US3862141
Folder: Visit 1 Day 1
Form: Pregnancy Test
Generated On: 10 Jun 2021 10:07:51
Test performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered empty; reason for change Data Entry Error	Shetel Anassi (b) (4) (b) (4)	20 Oct 2020 18:19:42
User entered 'Urine (URINE)'	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:34:48

US3862141
Folder: Visit 1 Day 1
Form: Pregnancy Test
Generated On: 10 Jun 2021 10:07:51
Result

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered empty; reason for change Data Entry Error	Shetel Anassi (b) (4) (b) (4)	20 Oct 2020 18:19:42
User entered 'Negative (NEGATIVE)'	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:34:48

US3862141
Folder: Visit 1 Day 1
Form: Pregnancy Test
Generated On: 10 Jun 2021 10:07:51
Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered empty; reason for change Data Entry Error	Shetel Anassi (b) (4) (b) (4)	20 Oct 2020 18:19:42
User entered 'No (N)'	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:34:48

US3862141
Folder: Visit 1 Day 1
Form: Pregnancy Test
Generated On: 10 Jun 2021 10:07:51
Collection date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:49:55
User closed query 'Please confirm - if no sample was collected, there should be no collection date/time entered. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:54:23
Query 'Please confirm - if no sample was collected, there should be no collection date/time entered. ' answered with 'Data Corrected ' (Site from CRA).	Shetel Anassi (b) (4) (b) (4)	20 Oct 2020 18:19:56
User entered empty; reason for change Data Entry Error	Shetel Anassi (b) (4) (b) (4)	20 Oct 2020 18:19:42
User opened query 'Please confirm - if no sample was collected, there should be no collection date/time entered. ' (Site from CRA).	(b) (4), (b) (6)	22 Sep 2020 00:02:28
User entered '08 Sep 2020'	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:34:48

US3862141
Folder: Visit 1 Day 1
Form: Pregnancy Test
Generated On: 10 Jun 2021 10:07:51
Collection time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered empty; reason for change Data Entry Error	Shetel Anassi (b) (4) (b) (4)	20 Oct 2020 18:19:42
User entered '12:50'	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:34:48

US3862141
Folder: Visit 1 Day 1
Form: Pregnancy Test
Generated On: 10 Jun 2021 10:07:51
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User entered empty.	System	20 Oct 2020 18:19:42
User entered '08 Sep 2020 12:50'	System	08 Sep 2020 19:34:48

US3862141
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 10:07:51
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered 'Yes (Y)'	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 17:55:18

US3862141
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 10:07:51
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered empty.	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 17:55:18

US3862141
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 10:07:51
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered empty.	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 17:55:18

US3862141
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 10:07:51
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User entered 'MRNA-1273 OR PLACEBO'	System	08 Sep 2020 17:55:18

US3862141
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 10:07:51
What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered '08 Sep 2020'	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 17:55:18

FDA-CBER-2022-1614-3766372

US3862141
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 10:07:51
What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered '12:45'	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 17:55:18

US3862141
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 10:07:51
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User entered '08 Sep 2020 12:45'	System	08 Sep 2020 17:55:18

FDA-CBER-2022-1614-3766374

US3862141
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 10:07:51
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered 'Left Arm (LEFT ARM)'	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 17:55:18

US3862141
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 10:07:51
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User entered 'ONCE'	System	08 Sep 2020 17:55:18

FDA-CBER-2022-1614-3766376

US3862141
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 10:07:51
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User entered 'INTRAMUSCULAR'	System	08 Sep 2020 17:55:18

FDA-CBER-2022-1614-3766377

US3862141
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 10:07:51
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered 'Yes (Y)'	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 17:55:50

FDA-CBER-2022-1614-3766378

US3862141
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 10:07:51
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered '08 Sep 2020'	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 17:55:50

US3862141
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 10:07:51
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered '12:11'	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 17:55:50

US3862141
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 10:07:51
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User entered '08 Sep 2020 12:11'	System	08 Sep 2020 17:55:50

US3862141
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab
Generated On: 10 Jun 2021 10:07:51
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered '08 Sep 2020'	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:37:12

US3862141
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 10:07:51
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:37:12

US3862141
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 10:07:51
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered 'Yes (Y)'	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:37:12

FDA-CBER-2022-1614-3766384

US3862141
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 10:07:51
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered '12:52'	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:37:12

FDA-CBER-2022-1614-3766385

US3862141
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 10:07:51
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User entered '08 Sep 2020 12:52'	System	08 Sep 2020 19:37:12

FDA-CBER-2022-1614-3766386

US3862141
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 10:07:51
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:37:12

FDA-CBER-2022-1614-3766387

US3862141
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 10:07:51
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered 'No (N)'	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:37:12

US3862141
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 10:07:51
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered empty.	Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 19:37:12

FDA-CBER-2022-1614-3766389

US3862141
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 10:07:51
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User entered empty.	System	08 Sep 2020 19:37:12

US3862141
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 10 Jun 2021 10:07:51
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered 'Yes (Y)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:49:23

US3862141
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 10 Jun 2021 10:07:51
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User entered '1'	System	14 Sep 2020 14:49:23

FDA-CBER-2022-1614-3766392

US3862141
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 10:07:51
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
Data entry locked.	System	08 Sep 2020 17:55:18
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 17:55:18

US3862141
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 10:07:51
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-08T13:09:36', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '5ea52373-a6da-4163-b1ba-e7f66f5eb6c4'	System	08 Sep 2020 18:10:27
User entered 'Yes (Y)'	System	08 Sep 2020 18:10:27

FDA-CBER-2022-1614-3766394

US3862141
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 10:07:51
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-08T13:10:05', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '5ea52373-a6da-4163-b1ba-e7f66f5eb6c4'	System	08 Sep 2020 18:10:27
User entered '98.4'	System	08 Sep 2020 18:10:27

US3862141
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 10:07:51
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-08T13:10:10', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '5ea52373-a6da-4163-b1ba-e7f66f5eb6c4'	System	08 Sep 2020 18:10:27
User entered 'No (N)'	System	08 Sep 2020 18:10:27

FDA-CBER-2022-1614-3766396

US3862141
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 10:07:51
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-08T13:10:23', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '5ea52373-a6da-4163-b1ba-e7f66f5eb6c4'	System	08 Sep 2020 18:10:27
User entered '08 Sep 2020 13:10'	System	08 Sep 2020 18:10:27

FDA-CBER-2022-1614-3766397

US3862141
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 10:07:51
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
User entered '08 Sep 2020 13:05'	System	08 Sep 2020 17:55:18

FDA-CBER-2022-1614-3766398

US3862141
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 10:07:51
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
User entered '08 Sep 2020 15:35'	System	08 Sep 2020 17:55:18

FDA-CBER-2022-1614-3766399

US3862141
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 10:07:51
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
Data entry locked.	System	08 Sep 2020 17:55:18
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 17:55:18

US3862141
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 10:07:51
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-08T17:45:34', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'e4293f05-8eb5-45aa-acf5-c6a8b475e9b1'	System	08 Sep 2020 22:46:09
User entered 'Yes (Y)'	System	08 Sep 2020 22:46:09

FDA-CBER-2022-1614-3766401

US3862141
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 10:07:51
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-08T17:45:49', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'e4293f05-8eb5-45aa-acf5-c6a8b475e9b1'	System	08 Sep 2020 22:46:09
User entered '97.8'	System	08 Sep 2020 22:46:09

FDA-CBER-2022-1614-3766402

US3862141
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 10:07:51
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-08T17:45:55', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'e4293f05-8eb5-45aa-acf5-c6a8b475e9b1'	System	08 Sep 2020 22:46:09
User entered 'No (N)'	System	08 Sep 2020 22:46:09

FDA-CBER-2022-1614-3766403

US3862141
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 10:07:51
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-08T17:46:05', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'e4293f05-8eb5-45aa-acf5-c6a8b475e9b1'	System	08 Sep 2020 22:46:09
User entered '08 Sep 2020 17:46'	System	08 Sep 2020 22:46:09

FDA-CBER-2022-1614-3766404

US3862141
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 10:07:51
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
User entered '08 Sep 2020 16:30'	System	08 Sep 2020 17:55:18

FDA-CBER-2022-1614-3766405

US3862141
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 10:07:51
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 17:55:18

FDA-CBER-2022-1614-3766406

US3862141
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 10:07:51
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
Data entry locked.	System	08 Sep 2020 17:55:18
User entered 'Day 2'	System	08 Sep 2020 17:55:18

FDA-CBER-2022-1614-3766407

US3862141
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 10:07:51
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-09T14:48:48', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'ad4e0df1-d2f4-4950-96dc-d9ea0ff90f0d'	System	09 Sep 2020 19:49:37
User entered 'Yes (Y)'	System	09 Sep 2020 19:49:37

FDA-CBER-2022-1614-3766408

US3862141
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 10:07:51
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-09T14:49:05', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'ad4e0df1-d2f4-4950-96dc-d9ea0ff90f0d'	System	09 Sep 2020 19:49:37
User entered '97.4'	System	09 Sep 2020 19:49:37

FDA-CBER-2022-1614-3766409

US3862141
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 10:07:51
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-09T14:49:21', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'ad4e0df1-d2f4-4950-96dc-d9ea0ff90f0d'	System	09 Sep 2020 19:49:37
User entered 'No (N)'	System	09 Sep 2020 19:49:37

FDA-CBER-2022-1614-3766410

US3862141
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 10:07:51
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-09T14:49:35', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'ad4e0df1-d2f4-4950-96dc-d9ea0ff90f0d'	System	09 Sep 2020 19:49:37
User entered '09 Sep 2020 14:49'	System	09 Sep 2020 19:49:37

FDA-CBER-2022-1614-3766411

US3862141
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 10:07:51
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 17:55:18

FDA-CBER-2022-1614-3766412

US3862141
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 10:07:51
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 17:55:18

FDA-CBER-2022-1614-3766413

US3862141
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 10:07:51
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
Data entry locked.	System	08 Sep 2020 17:55:18
User entered 'Day 3'	System	08 Sep 2020 17:55:18

FDA-CBER-2022-1614-3766414

US3862141
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 10:07:51
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-10T13:56:00', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'f49594db-b2f8-47f9-b7b0-75a4b39ebe2b'	System	10 Sep 2020 18:56:29
User entered 'Yes (Y)'	System	10 Sep 2020 18:56:29

FDA-CBER-2022-1614-3766415

US3862141
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 10:07:51
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-10T13:56:12', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'f49594db-b2f8-47f9-b7b0-75a4b39ebe2b'	System	10 Sep 2020 18:56:29
User entered '98.1'	System	10 Sep 2020 18:56:29

FDA-CBER-2022-1614-3766416

US3862141
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 10:07:51
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-10T13:56:17', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'f49594db-b2f8-47f9-b7b0-75a4b39ebe2b'	System	10 Sep 2020 18:56:29
User entered 'No (N)'	System	10 Sep 2020 18:56:29

FDA-CBER-2022-1614-3766417

US3862141
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 10:07:51
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-10T13:56:27', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'f49594db-b2f8-47f9-b7b0-75a4b39ebe2b'	System	10 Sep 2020 18:56:29
User entered '10 Sep 2020 13:56'	System	10 Sep 2020 18:56:29

FDA-CBER-2022-1614-3766418

US3862141
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 10:07:51
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 17:55:18

FDA-CBER-2022-1614-3766419

US3862141
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 10:07:51
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 17:55:18

FDA-CBER-2022-1614-3766420

US3862141
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 10:07:51
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
Data entry locked.	System	08 Sep 2020 17:55:18
User entered 'Day 4'	System	08 Sep 2020 17:55:18

FDA-CBER-2022-1614-3766421

US3862141
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 10:07:51
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-11T12:38:55', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '7960e57e-ff79-4235-ac3a-2ff3738a0ec2'	System	11 Sep 2020 17:39:20
User entered 'Yes (Y)'	System	11 Sep 2020 17:39:20

FDA-CBER-2022-1614-3766422

US3862141
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 10:07:51
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-11T12:39:04', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '7960e57e-ff79-4235-ac3a-2ff3738a0ec2'	System	11 Sep 2020 17:39:20
User entered '98.2'	System	11 Sep 2020 17:39:20

FDA-CBER-2022-1614-3766423

US3862141
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 10:07:51
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-11T12:39:08', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '7960e57e-ff79-4235-ac3a-2ff3738a0ec2'	System	11 Sep 2020 17:39:20
User entered 'No (N)'	System	11 Sep 2020 17:39:20

FDA-CBER-2022-1614-3766424

US3862141
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 10:07:51
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-11T12:39:17', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '7960e57e-ff79-4235-ac3a-2ff3738a0ec2'	System	11 Sep 2020 17:39:20
User entered '11 Sep 2020 12:39'	System	11 Sep 2020 17:39:20

FDA-CBER-2022-1614-3766425

US3862141
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 10:07:51
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 17:55:18

FDA-CBER-2022-1614-3766426

US3862141
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 10:07:51
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 17:55:18

FDA-CBER-2022-1614-3766427

US3862141
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 10:07:51
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
Data entry locked.	System	08 Sep 2020 17:55:18
User entered 'Day 5'	System	08 Sep 2020 17:55:18

FDA-CBER-2022-1614-3766428

US3862141
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 10:07:51
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-12T14:30:37', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '53765b5a-b8d0-410c-a3f9-5d2990d802f9'	System	12 Sep 2020 19:31:00
User entered 'Yes (Y)'	System	12 Sep 2020 19:31:00

FDA-CBER-2022-1614-3766429

US3862141
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 10:07:51
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-12T14:30:46', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '53765b5a-b8d0-410c-a3f9-5d2990d802f9'	System	12 Sep 2020 19:31:00
User entered '97.6'	System	12 Sep 2020 19:31:00

FDA-CBER-2022-1614-3766430

US3862141
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 10:07:51
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-12T14:30:51', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '53765b5a-b8d0-410c-a3f9-5d2990d802f9'	System	12 Sep 2020 19:31:00
User entered 'No (N)'	System	12 Sep 2020 19:31:00

FDA-CBER-2022-1614-3766431

US3862141
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 10:07:51
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-12T14:30:58', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '53765b5a-b8d0-410c-a3f9-5d2990d802f9'	System	12 Sep 2020 19:31:00
User entered '12 Sep 2020 14:30'	System	12 Sep 2020 19:31:00

FDA-CBER-2022-1614-3766432

US3862141
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 10:07:51
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 17:55:18

FDA-CBER-2022-1614-3766433

US3862141
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 10:07:51
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 17:55:18

FDA-CBER-2022-1614-3766434

US3862141
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 10:07:51
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
Data entry locked.	System	08 Sep 2020 17:55:18
User entered 'Day 6'	System	08 Sep 2020 17:55:18

FDA-CBER-2022-1614-3766435

US3862141
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 10:07:51
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-13T16:02:36', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '55dc1ce4-8b4d-4bfa-a563-49738b8a8a60'	System	13 Sep 2020 21:03:01
User entered 'Yes (Y)'	System	13 Sep 2020 21:03:01

FDA-CBER-2022-1614-3766436

US3862141
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 10:07:51
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-13T16:02:49', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '55dc1ce4-8b4d-4bfa-a563-49738b8a8a60'	System	13 Sep 2020 21:03:01
User entered '97.9'	System	13 Sep 2020 21:03:01

FDA-CBER-2022-1614-3766437

US3862141
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 10:07:51
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-13T16:02:53', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '55dc1ce4-8b4d-4bfa-a563-49738b8a8a60'	System	13 Sep 2020 21:03:01
User entered 'No (N)'	System	13 Sep 2020 21:03:01

FDA-CBER-2022-1614-3766438

US3862141
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 10:07:51
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-13T16:02:59', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '55dc1ce4-8b4d-4bfa-a563-49738b8a8a60'	System	13 Sep 2020 21:03:01
User entered '13 Sep 2020 16:02'	System	13 Sep 2020 21:03:01

FDA-CBER-2022-1614-3766439

US3862141
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 10:07:51
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 17:55:18

FDA-CBER-2022-1614-3766440

US3862141
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 10:07:51
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 17:55:18

FDA-CBER-2022-1614-3766441

US3862141
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 10:07:51
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
Data entry locked.	System	08 Sep 2020 17:55:18
User entered 'Day 7'	System	08 Sep 2020 17:55:18

FDA-CBER-2022-1614-3766442

US3862141
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 10:07:51
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-14T12:51:25', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '18203722-9063-4b03-9ca2-c7e84ccdbcf9'	System	14 Sep 2020 17:51:43
User entered 'Yes (Y)'	System	14 Sep 2020 17:51:43

FDA-CBER-2022-1614-3766443

US3862141
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 10:07:51
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-14T12:51:32', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '18203722-9063-4b03-9ca2-c7e84ccdbcf9'	System	14 Sep 2020 17:51:43
User entered '97.7'	System	14 Sep 2020 17:51:43

FDA-CBER-2022-1614-3766444

US3862141
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 10:07:51
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-14T12:51:36', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '18203722-9063-4b03-9ca2-c7e84ccdbcf9'	System	14 Sep 2020 17:51:43
User entered 'No (N)'	System	14 Sep 2020 17:51:43

FDA-CBER-2022-1614-3766445

US3862141
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 10:07:51
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-14T12:51:41', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '18203722-9063-4b03-9ca2-c7e84ccdbcf9'	System	14 Sep 2020 17:51:43
User entered '14 Sep 2020 12:51'	System	14 Sep 2020 17:51:43

FDA-CBER-2022-1614-3766446

US3862141
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 10:07:51
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 17:55:18

FDA-CBER-2022-1614-3766447

US3862141
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 10:07:51
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 17:55:18

FDA-CBER-2022-1614-3766448

US3862141
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 10:07:51
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
Data entry locked.	System	08 Sep 2020 17:55:18
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 17:55:18

US3862141
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 10:07:51
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-08T13:10:55', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '253a7a91-6656-4a94-9fc0-b7825b11b652'	System	08 Sep 2020 18:11:22
User entered 'None (1)'	System	08 Sep 2020 18:11:22

US3862141
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 10:07:51
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-08T13:11:01', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '253a7a91-6656-4a94-9fc0-b7825b11b652'	System	08 Sep 2020 18:11:22
User entered 'No (N)'	System	08 Sep 2020 18:11:22

US3862141
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 10:07:51
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-08T13:11:06', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '253a7a91-6656-4a94-9fc0-b7825b11b652'	System	08 Sep 2020 18:11:22
User entered 'No (N)'	System	08 Sep 2020 18:11:22

US3862141
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 10:07:51
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-08T13:11:13', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '253a7a91-6656-4a94-9fc0-b7825b11b652'	System	08 Sep 2020 18:11:22
User entered 'None (1)'	System	08 Sep 2020 18:11:22

US3862141
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 10:07:51
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-08T13:11:18', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '253a7a91-6656-4a94-9fc0-b7825b11b652'	System	08 Sep 2020 18:11:22
User entered '08 Sep 2020 13:11'	System	08 Sep 2020 18:11:22

FDA-CBER-2022-1614-3766454

US3862141
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 10:07:51
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
User entered '08 Sep 2020 13:05'	System	08 Sep 2020 17:55:18

FDA-CBER-2022-1614-3766455

US3862141
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 10:07:51
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
User entered '08 Sep 2020 15:35'	System	08 Sep 2020 17:55:18

FDA-CBER-2022-1614-3766456

US3862141
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 10:07:51
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
Data entry locked.	System	08 Sep 2020 17:55:18
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 17:55:18

US3862141
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 10:07:51
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-08T17:46:19', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'b9d776e9-59c4-41fe-a5b3-ba8535feaa5d'	System	08 Sep 2020 22:46:42
User entered 'None (1)'	System	08 Sep 2020 22:46:42

FDA-CBER-2022-1614-3766458

US3862141
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 10:07:51
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-08T17:46:23', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'b9d776e9-59c4-41fe-a5b3-ba8535feaa5d'	System	08 Sep 2020 22:46:42
User entered 'No (N)'	System	08 Sep 2020 22:46:42

FDA-CBER-2022-1614-3766459

US3862141
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 10:07:51
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-08T17:46:27', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'b9d776e9-59c4-41fe-a5b3-ba8535feaa5d'	System	08 Sep 2020 22:46:42
User entered 'No (N)'	System	08 Sep 2020 22:46:42

US3862141
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 10:07:51
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-08T17:46:35', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'b9d776e9-59c4-41fe-a5b3-ba8535feaa5d'	System	08 Sep 2020 22:46:42
User entered 'None (1)'	System	08 Sep 2020 22:46:42

FDA-CBER-2022-1614-3766461

US3862141
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 10:07:51
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-08T17:46:40', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'b9d776e9-59c4-41fe-a5b3-ba8535feaa5d'	System	08 Sep 2020 22:46:42
User entered '08 Sep 2020 17:46'	System	08 Sep 2020 22:46:42

FDA-CBER-2022-1614-3766462

US3862141
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 10:07:51
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
User entered '08 Sep 2020 16:30'	System	08 Sep 2020 17:55:18

FDA-CBER-2022-1614-3766463

US3862141
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 10:07:51
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 17:55:18

FDA-CBER-2022-1614-3766464

US3862141
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 10:07:51
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
Data entry locked.	System	08 Sep 2020 17:55:18
User entered 'Day 2'	System	08 Sep 2020 17:55:18

US3862141
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 10:07:51
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-09T14:49:52', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '3f376c98-e63b-4aec-82ef-9ab10353016b'	System	09 Sep 2020 19:50:41
User entered 'None (1)'	System	09 Sep 2020 19:50:41

FDA-CBER-2022-1614-3766466

US3862141
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 10:07:51
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-09T14:49:58', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '3f376c98-e63b-4aec-82ef-9ab10353016b'	System	09 Sep 2020 19:50:41
User entered 'No (N)'	System	09 Sep 2020 19:50:41

US3862141
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 10:07:51
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-09T14:50:29', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '3f376c98-e63b-4aec-82ef-9ab10353016b'	System	09 Sep 2020 19:50:41
User entered 'No (N)'	System	09 Sep 2020 19:50:41

US3862141
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 10:07:51
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-09T14:50:35', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '3f376c98-e63b-4aec-82ef-9ab10353016b'	System	09 Sep 2020 19:50:41
User entered 'None (1)'	System	09 Sep 2020 19:50:41

US3862141
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 10:07:51
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-09T14:50:40', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '3f376c98-e63b-4aec-82ef-9ab10353016b'	System	09 Sep 2020 19:50:41
User entered '09 Sep 2020 14:50'	System	09 Sep 2020 19:50:41

FDA-CBER-2022-1614-3766470

US3862141
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 10:07:51
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 17:55:18

FDA-CBER-2022-1614-3766471

US3862141
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 10:07:51
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 17:55:18

FDA-CBER-2022-1614-3766472

US3862141
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 10:07:51
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
Data entry locked.	System	08 Sep 2020 17:55:18
User entered 'Day 3'	System	08 Sep 2020 17:55:18

US3862141
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 10:07:51
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-10T13:56:55', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '1b695659-dc3c-4118-91c9-f6796fa6d650'	System	10 Sep 2020 18:57:19
User entered 'None (1)'	System	10 Sep 2020 18:57:19

FDA-CBER-2022-1614-3766474

US3862141
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 10:07:51
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-10T13:56:59', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '1b695659-dc3c-4118-91c9-f6796fa6d650'	System	10 Sep 2020 18:57:19
User entered 'No (N)'	System	10 Sep 2020 18:57:19

US3862141
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 10:07:51
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-10T13:57:04', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '1b695659-dc3c-4118-91c9-f6796fa6d650'	System	10 Sep 2020 18:57:19
User entered 'No (N)'	System	10 Sep 2020 18:57:19

FDA-CBER-2022-1614-3766476

US3862141
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 10:07:51
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-10T13:57:10', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '1b695659-dc3c-4118-91c9-f6796fa6d650'	System	10 Sep 2020 18:57:19
User entered 'None (1)'	System	10 Sep 2020 18:57:19

US3862141
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 10:07:51
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-10T13:57:17', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '1b695659-dc3c-4118-91c9-f6796fa6d650'	System	10 Sep 2020 18:57:19
User entered '10 Sep 2020 13:57'	System	10 Sep 2020 18:57:19

FDA-CBER-2022-1614-3766478

US3862141
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 10:07:51
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 17:55:18

FDA-CBER-2022-1614-3766479

US3862141
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 10:07:51
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 17:55:18

FDA-CBER-2022-1614-3766480

US3862141
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 10:07:51
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
Data entry locked.	System	08 Sep 2020 17:55:18
User entered 'Day 4'	System	08 Sep 2020 17:55:18

FDA-CBER-2022-1614-3766481

US3862141
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 10:07:51
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-11T12:39:38', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '365bcc5b-a1fb-4b10-97eb-1ed26427951e'	System	11 Sep 2020 17:40:11
User entered 'None (1)'	System	11 Sep 2020 17:40:11

FDA-CBER-2022-1614-3766482

US3862141
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 10:07:51
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-11T12:39:47', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '365bcc5b-a1fb-4b10-97eb-1ed26427951e'	System	11 Sep 2020 17:40:11
User entered 'No (N)'	System	11 Sep 2020 17:40:11

FDA-CBER-2022-1614-3766483

US3862141
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 10:07:51
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-11T12:39:53', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '365bcc5b-a1fb-4b10-97eb-1ed26427951e'	System	11 Sep 2020 17:40:11
User entered 'No (N)'	System	11 Sep 2020 17:40:11

FDA-CBER-2022-1614-3766484

US3862141
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 10:07:51
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-11T12:39:58', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '365bcc5b-a1fb-4b10-97eb-1ed26427951e'	System	11 Sep 2020 17:40:11
User entered 'None (1)'	System	11 Sep 2020 17:40:11

FDA-CBER-2022-1614-3766485

US3862141
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 10:07:51
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-11T12:40:04', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '365bcc5b-a1fb-4b10-97eb-1ed26427951e'	System	11 Sep 2020 17:40:11
User entered '11 Sep 2020 12:40'	System	11 Sep 2020 17:40:11

US3862141
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 10:07:51
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 17:55:18

FDA-CBER-2022-1614-3766487

US3862141
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 10:07:51
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 17:55:18

FDA-CBER-2022-1614-3766488

US3862141
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 10:07:51
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
Data entry locked.	System	08 Sep 2020 17:55:18
User entered 'Day 5'	System	08 Sep 2020 17:55:18

US3862141
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 10:07:51
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-12T14:31:05', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'd4583b20-71af-453f-bc46-e16774f5b8ed'	System	12 Sep 2020 19:31:37
User entered 'None (1)'	System	12 Sep 2020 19:31:37

FDA-CBER-2022-1614-3766490

US3862141
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 10:07:51
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-12T14:31:12', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'd4583b20-71af-453f-bc46-e16774f5b8ed'	System	12 Sep 2020 19:31:37
User entered 'No (N)'	System	12 Sep 2020 19:31:37

US3862141
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 10:07:51
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-12T14:31:18', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'd4583b20-71af-453f-bc46-e16774f5b8ed'	System	12 Sep 2020 19:31:37
User entered 'No (N)'	System	12 Sep 2020 19:31:37

FDA-CBER-2022-1614-3766492

US3862141
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 10:07:51
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-12T14:31:28', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'd4583b20-71af-453f-bc46-e16774f5b8ed'	System	12 Sep 2020 19:31:37
User entered 'None (1)'	System	12 Sep 2020 19:31:37

FDA-CBER-2022-1614-3766493

US3862141
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 10:07:51
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-12T14:31:33', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'd4583b20-71af-453f-bc46-e16774f5b8ed'	System	12 Sep 2020 19:31:37
User entered '12 Sep 2020 14:31'	System	12 Sep 2020 19:31:37

FDA-CBER-2022-1614-3766494

US3862141
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 10:07:51
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 17:55:18

FDA-CBER-2022-1614-3766495

US3862141
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 10:07:51
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 17:55:18

FDA-CBER-2022-1614-3766496

US3862141
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 10:07:51
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
Data entry locked.	System	08 Sep 2020 17:55:18
User entered 'Day 6'	System	08 Sep 2020 17:55:18

FDA-CBER-2022-1614-3766497

US3862141
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 10:07:51
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-13T16:03:12', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '589f628b-a7b3-4206-a7ba-a84d3a00ff1a'	System	13 Sep 2020 21:03:34
User entered 'None (1)'	System	13 Sep 2020 21:03:34

FDA-CBER-2022-1614-3766498

US3862141
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 10:07:51
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-13T16:03:18', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '589f628b-a7b3-4206-a7ba-a84d3a00ff1a'	System	13 Sep 2020 21:03:34
User entered 'No (N)'	System	13 Sep 2020 21:03:34

FDA-CBER-2022-1614-3766499

US3862141
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 10:07:51
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-13T16:03:22', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '589f628b-a7b3-4206-a7ba-a84d3a00ff1a'	System	13 Sep 2020 21:03:34
User entered 'No (N)'	System	13 Sep 2020 21:03:34

FDA-CBER-2022-1614-3766500

US3862141
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 10:07:51
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-13T16:03:27', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '589f628b-a7b3-4206-a7ba-a84d3a00ff1a'	System	13 Sep 2020 21:03:34
User entered 'None (1)'	System	13 Sep 2020 21:03:34

FDA-CBER-2022-1614-3766501

US3862141
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 10:07:51
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-13T16:03:32', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '589f628b-a7b3-4206-a7ba-a84d3a00ff1a'	System	13 Sep 2020 21:03:34
User entered '13 Sep 2020 16:03'	System	13 Sep 2020 21:03:34

FDA-CBER-2022-1614-3766502

US3862141
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 10:07:51
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 17:55:18

FDA-CBER-2022-1614-3766503

US3862141
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 10:07:51
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 17:55:18

FDA-CBER-2022-1614-3766504

US3862141
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 10:07:51
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
Data entry locked.	System	08 Sep 2020 17:55:18
User entered 'Day 7'	System	08 Sep 2020 17:55:18

US3862141
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 10:07:51
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-14T12:51:46', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '51598fc5-a8f4-4f61-8790-c43ccd8a303d'	System	14 Sep 2020 17:52:19
User entered 'None (1)'	System	14 Sep 2020 17:52:19

FDA-CBER-2022-1614-3766506

US3862141
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 10:07:51
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-14T12:51:50', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '51598fc5-a8f4-4f61-8790-c43ccd8a303d'	System	14 Sep 2020 17:52:19
User entered 'No (N)'	System	14 Sep 2020 17:52:19

FDA-CBER-2022-1614-3766507

US3862141
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 10:07:51
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-14T12:52:01', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '51598fc5-a8f4-4f61-8790-c43ccd8a303d'	System	14 Sep 2020 17:52:19
User entered 'No (N)'	System	14 Sep 2020 17:52:19

FDA-CBER-2022-1614-3766508

US3862141
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 10:07:51
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-14T12:52:05', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '51598fc5-a8f4-4f61-8790-c43ccd8a303d'	System	14 Sep 2020 17:52:19
User entered 'None (1)'	System	14 Sep 2020 17:52:19

US3862141
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 10:07:51
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-14T12:52:09', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '51598fc5-a8f4-4f61-8790-c43ccd8a303d'	System	14 Sep 2020 17:52:19
User entered '14 Sep 2020 12:52'	System	14 Sep 2020 17:52:19

FDA-CBER-2022-1614-3766510

US3862141
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 10:07:51
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 17:55:18

US3862141
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 10:07:51
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 17:55:18

FDA-CBER-2022-1614-3766512

US3862141
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 10:07:51
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
Data entry locked.	System	08 Sep 2020 17:55:18
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 17:55:18

FDA-CBER-2022-1614-3766513

US3862141
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 10:07:51
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-08T13:11:34', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'de14917f-f70f-4c38-9a93-dc54d352a7c1'	System	08 Sep 2020 18:12:10
User entered 'None (0)'	System	08 Sep 2020 18:12:10

FDA-CBER-2022-1614-3766514

US3862141
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 10:07:51
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-08T13:11:38', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'de14917f-f70f-4c38-9a93-dc54d352a7c1'	System	08 Sep 2020 18:12:10
User entered 'None (0)'	System	08 Sep 2020 18:12:10

FDA-CBER-2022-1614-3766515

US3862141
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 10:07:51
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-08T13:11:42', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'de14917f-f70f-4c38-9a93-dc54d352a7c1'	System	08 Sep 2020 18:12:10
User entered 'None (0)'	System	08 Sep 2020 18:12:10

FDA-CBER-2022-1614-3766516

US3862141
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 10:07:51
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-08T13:11:47', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'de14917f-f70f-4c38-9a93-dc54d352a7c1'	System	08 Sep 2020 18:12:10
User entered 'None (0)'	System	08 Sep 2020 18:12:10

FDA-CBER-2022-1614-3766517

US3862141
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 10:07:51
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-08T13:11:50', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'de14917f-f70f-4c38-9a93-dc54d352a7c1'	System	08 Sep 2020 18:12:10
User entered 'None (0)'	System	08 Sep 2020 18:12:10

FDA-CBER-2022-1614-3766518

US3862141
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 10:07:51
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-08T13:11:53', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'de14917f-f70f-4c38-9a93-dc54d352a7c1'	System	08 Sep 2020 18:12:10
User entered 'None (0)'	System	08 Sep 2020 18:12:10

FDA-CBER-2022-1614-3766519

US3862141
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 10:07:51
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)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-08T13:11:59', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'de14917f-f70f-4c38-9a93-dc54d352a7c1'	System	08 Sep 2020 18:12:10
User entered 'No (N)'	System	08 Sep 2020 18:12:10

FDA-CBER-2022-1614-3766520

US3862141
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 10:07:51
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-08T13:12:04', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'de14917f-f70f-4c38-9a93-dc54d352a7c1'	System	08 Sep 2020 18:12:10
User entered '08 Sep 2020 13:12'	System	08 Sep 2020 18:12:10

FDA-CBER-2022-1614-3766521

US3862141
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 10:07:51
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
User entered '08 Sep 2020 13:05'	System	08 Sep 2020 17:55:18

FDA-CBER-2022-1614-3766522

US3862141
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 10:07:51
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
User entered '08 Sep 2020 15:35'	System	08 Sep 2020 17:55:18

FDA-CBER-2022-1614-3766523

US3862141
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 10:07:51
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
Data entry locked.	System	08 Sep 2020 17:55:18
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 17:55:18

US3862141
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 10:07:51
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-08T17:46:50', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '7dffb0c8-9112-4b41-985e-2c6f32598108'	System	08 Sep 2020 22:47:23
User entered 'None (0)'	System	08 Sep 2020 22:47:23

FDA-CBER-2022-1614-3766525

US3862141
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 10:07:51
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-08T17:46:57', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '7dffb0c8-9112-4b41-985e-2c6f32598108'	System	08 Sep 2020 22:47:23
User entered 'None (0)'	System	08 Sep 2020 22:47:23

FDA-CBER-2022-1614-3766526

US3862141
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 10:07:51
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-08T17:47:01', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '7dffb0c8-9112-4b41-985e-2c6f32598108'	System	08 Sep 2020 22:47:23
User entered 'None (0)'	System	08 Sep 2020 22:47:23

FDA-CBER-2022-1614-3766527

US3862141
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 10:07:51
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-08T17:47:04', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '7dffb0c8-9112-4b41-985e-2c6f32598108'	System	08 Sep 2020 22:47:23
User entered 'None (0)'	System	08 Sep 2020 22:47:23

FDA-CBER-2022-1614-3766528

US3862141
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 10:07:51
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-08T17:47:07', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '7dffb0c8-9112-4b41-985e-2c6f32598108'	System	08 Sep 2020 22:47:23
User entered 'None (0)'	System	08 Sep 2020 22:47:23

FDA-CBER-2022-1614-3766529

US3862141
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 10:07:51
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-08T17:47:10', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '7dffb0c8-9112-4b41-985e-2c6f32598108'	System	08 Sep 2020 22:47:23
User entered 'None (0)'	System	08 Sep 2020 22:47:23

US3862141
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 10:07:51
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)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-08T17:47:16', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '7dffb0c8-9112-4b41-985e-2c6f32598108'	System	08 Sep 2020 22:47:23
User entered 'No (N)'	System	08 Sep 2020 22:47:23

FDA-CBER-2022-1614-3766531

US3862141
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 10:07:51
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-08T17:47:20', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '7dffb0c8-9112-4b41-985e-2c6f32598108'	System	08 Sep 2020 22:47:23
User entered '08 Sep 2020 17:47'	System	08 Sep 2020 22:47:23

FDA-CBER-2022-1614-3766532

US3862141
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 10:07:51
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
User entered '08 Sep 2020 16:30'	System	08 Sep 2020 17:55:18

FDA-CBER-2022-1614-3766533

US3862141
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 10:07:51
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 17:55:18

FDA-CBER-2022-1614-3766534

US3862141
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 10:07:51
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
Data entry locked.	System	08 Sep 2020 17:55:18
User entered 'Day 2'	System	08 Sep 2020 17:55:18

US3862141
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 10:07:51
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-09T14:51:02', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '543f91a5-89c7-47bf-b905-74507576a281'	System	09 Sep 2020 19:51:58
User entered 'None (0)'	System	09 Sep 2020 19:51:58

FDA-CBER-2022-1614-3766536

US3862141
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 10:07:51
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-09T14:51:13', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '543f91a5-89c7-47bf-b905-74507576a281'	System	09 Sep 2020 19:51:58
User entered 'None (0)'	System	09 Sep 2020 19:51:58

US3862141
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 10:07:51
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-09T14:51:20', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '543f91a5-89c7-47bf-b905-74507576a281'	System	09 Sep 2020 19:51:58
User entered 'None (0)'	System	09 Sep 2020 19:51:58

FDA-CBER-2022-1614-3766538

US3862141
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 10:07:51
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-09T14:51:26', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '543f91a5-89c7-47bf-b905-74507576a281'	System	09 Sep 2020 19:51:58
User entered 'None (0)'	System	09 Sep 2020 19:51:58

US3862141
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 10:07:51
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-09T14:51:31', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '543f91a5-89c7-47bf-b905-74507576a281'	System	09 Sep 2020 19:51:58
User entered 'None (0)'	System	09 Sep 2020 19:51:58

US3862141
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 10:07:51
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-09T14:51:34', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '543f91a5-89c7-47bf-b905-74507576a281'	System	09 Sep 2020 19:51:58
User entered 'None (0)'	System	09 Sep 2020 19:51:58

US3862141
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 10:07:51
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)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-09T14:51:47', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '543f91a5-89c7-47bf-b905-74507576a281'	System	09 Sep 2020 19:51:58
User entered 'Yes (Y)'	System	09 Sep 2020 19:51:58

US3862141
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 10:07:51
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-09T14:51:57', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '543f91a5-89c7-47bf-b905-74507576a281'	System	09 Sep 2020 19:51:58
User entered '09 Sep 2020 14:51'	System	09 Sep 2020 19:51:58

US3862141
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 10:07:51
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 17:55:18

FDA-CBER-2022-1614-3766544

US3862141
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 10:07:51
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 17:55:18

FDA-CBER-2022-1614-3766545

US3862141
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 10:07:51
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
Data entry locked.	System	08 Sep 2020 17:55:18
User entered 'Day 3'	System	08 Sep 2020 17:55:18

FDA-CBER-2022-1614-3766546

US3862141
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 10:07:51
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-10T13:57:32', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '7115c7ed-592e-4bdf-a682-29eacb2933c6'	System	10 Sep 2020 18:58:18
User entered 'None (0)'	System	10 Sep 2020 18:58:18

FDA-CBER-2022-1614-3766547

US3862141
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 10:07:51
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-10T13:57:40', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '7115c7ed-592e-4bdf-a682-29eacb2933c6'	System	10 Sep 2020 18:58:18
User entered 'None (0)'	System	10 Sep 2020 18:58:18

FDA-CBER-2022-1614-3766548

US3862141
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 10:07:51
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-10T13:57:46', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '7115c7ed-592e-4bdf-a682-29eacb2933c6'	System	10 Sep 2020 18:58:18
User entered 'None (0)'	System	10 Sep 2020 18:58:18

FDA-CBER-2022-1614-3766549

US3862141
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 10:07:51
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-10T13:57:50', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '7115c7ed-592e-4bdf-a682-29eacb2933c6'	System	10 Sep 2020 18:58:18
User entered 'None (0)'	System	10 Sep 2020 18:58:18

FDA-CBER-2022-1614-3766550

US3862141
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 10:07:51
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-10T13:57:53', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '7115c7ed-592e-4bdf-a682-29eacb2933c6'	System	10 Sep 2020 18:58:18
User entered 'None (0)'	System	10 Sep 2020 18:58:18

FDA-CBER-2022-1614-3766551

US3862141
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 10:07:51
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-10T13:57:56', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '7115c7ed-592e-4bdf-a682-29eacb2933c6'	System	10 Sep 2020 18:58:18
User entered 'None (0)'	System	10 Sep 2020 18:58:18

FDA-CBER-2022-1614-3766552

US3862141
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 10:07:51
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)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-10T13:58:07', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '7115c7ed-592e-4bdf-a682-29eacb2933c6'	System	10 Sep 2020 18:58:18
User entered 'No (N)'	System	10 Sep 2020 18:58:18

US3862141
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 10:07:51
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-10T13:58:14', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '7115c7ed-592e-4bdf-a682-29eacb2933c6'	System	10 Sep 2020 18:58:18
User entered '10 Sep 2020 13:58'	System	10 Sep 2020 18:58:18

FDA-CBER-2022-1614-3766554

US3862141
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 10:07:51
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 17:55:18

FDA-CBER-2022-1614-3766555

US3862141
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 10:07:51
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 17:55:18

FDA-CBER-2022-1614-3766556

US3862141
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 10:07:51
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
Data entry locked.	System	08 Sep 2020 17:55:18
User entered 'Day 4'	System	08 Sep 2020 17:55:18

US3862141
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 10:07:51
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-11T12:40:11', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'bda25919-4907-464b-a0db-d6337a7d8a4a'	System	11 Sep 2020 17:40:47
User entered 'None (0)'	System	11 Sep 2020 17:40:47

FDA-CBER-2022-1614-3766558

US3862141
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 10:07:51
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-11T12:40:15', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'bda25919-4907-464b-a0db-d6337a7d8a4a'	System	11 Sep 2020 17:40:47
User entered 'None (0)'	System	11 Sep 2020 17:40:47

US3862141
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 10:07:51
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-11T12:40:18', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'bda25919-4907-464b-a0db-d6337a7d8a4a'	System	11 Sep 2020 17:40:47
User entered 'None (0)'	System	11 Sep 2020 17:40:47

FDA-CBER-2022-1614-3766560

US3862141
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 10:07:51
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-11T12:40:21', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'bda25919-4907-464b-a0db-d6337a7d8a4a'	System	11 Sep 2020 17:40:47
User entered 'None (0)'	System	11 Sep 2020 17:40:47

FDA-CBER-2022-1614-3766561

US3862141
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 10:07:51
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-11T12:40:25', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'bda25919-4907-464b-a0db-d6337a7d8a4a'	System	11 Sep 2020 17:40:47
User entered 'None (0)'	System	11 Sep 2020 17:40:47

FDA-CBER-2022-1614-3766562

US3862141
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 10:07:51
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-11T12:40:29', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'bda25919-4907-464b-a0db-d6337a7d8a4a'	System	11 Sep 2020 17:40:47
User entered 'None (0)'	System	11 Sep 2020 17:40:47

US3862141
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 10:07:51
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)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-11T12:40:38', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'bda25919-4907-464b-a0db-d6337a7d8a4a'	System	11 Sep 2020 17:40:47
User entered 'No (N)'	System	11 Sep 2020 17:40:47

FDA-CBER-2022-1614-3766564

US3862141
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 10:07:51
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-11T12:40:43', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'bda25919-4907-464b-a0db-d6337a7d8a4a'	System	11 Sep 2020 17:40:47
User entered '11 Sep 2020 12:40'	System	11 Sep 2020 17:40:47

US3862141
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 10:07:51
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 17:55:18

FDA-CBER-2022-1614-3766566

US3862141
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 10:07:51
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 17:55:18

FDA-CBER-2022-1614-3766567

US3862141
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 10:07:51
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
Data entry locked.	System	08 Sep 2020 17:55:18
User entered 'Day 5'	System	08 Sep 2020 17:55:18

FDA-CBER-2022-1614-3766568

US3862141
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 10:07:51
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-12T14:31:41', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'fae27f00-9c10-4e6f-92da-e3fb5f27298c'	System	12 Sep 2020 19:32:07
User entered 'None (0)'	System	12 Sep 2020 19:32:07

FDA-CBER-2022-1614-3766569

US3862141
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 10:07:51
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-12T14:31:44', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'fae27f00-9c10-4e6f-92da-e3fb5f27298c'	System	12 Sep 2020 19:32:07
User entered 'None (0)'	System	12 Sep 2020 19:32:07

FDA-CBER-2022-1614-3766570

US3862141
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 10:07:51
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-12T14:31:47', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'fae27f00-9c10-4e6f-92da-e3fb5f27298c'	System	12 Sep 2020 19:32:07
User entered 'None (0)'	System	12 Sep 2020 19:32:07

FDA-CBER-2022-1614-3766571

US3862141
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 10:07:51
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-12T14:31:50', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'fae27f00-9c10-4e6f-92da-e3fb5f27298c'	System	12 Sep 2020 19:32:07
User entered 'None (0)'	System	12 Sep 2020 19:32:07

FDA-CBER-2022-1614-3766572

US3862141
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 10:07:51
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-12T14:31:52', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'fae27f00-9c10-4e6f-92da-e3fb5f27298c'	System	12 Sep 2020 19:32:07
User entered 'None (0)'	System	12 Sep 2020 19:32:07

FDA-CBER-2022-1614-3766573

US3862141
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 10:07:51
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-12T14:31:55', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'fae27f00-9c10-4e6f-92da-e3fb5f27298c'	System	12 Sep 2020 19:32:07
User entered 'None (0)'	System	12 Sep 2020 19:32:07

FDA-CBER-2022-1614-3766574

US3862141
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 10:07:51
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)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-12T14:31:59', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'fae27f00-9c10-4e6f-92da-e3fb5f27298c'	System	12 Sep 2020 19:32:07
User entered 'No (N)'	System	12 Sep 2020 19:32:07

US3862141
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 10:07:51
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-12T14:32:04', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'fae27f00-9c10-4e6f-92da-e3fb5f27298c'	System	12 Sep 2020 19:32:07
User entered '12 Sep 2020 14:32'	System	12 Sep 2020 19:32:07

FDA-CBER-2022-1614-3766576

US3862141
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 10:07:51
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 17:55:18

FDA-CBER-2022-1614-3766577

US3862141
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 10:07:51
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 17:55:18

FDA-CBER-2022-1614-3766578

US3862141
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 10:07:51
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
Data entry locked.	System	08 Sep 2020 17:55:18
User entered 'Day 6'	System	08 Sep 2020 17:55:18

FDA-CBER-2022-1614-3766579

US3862141
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 10:07:51
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-13T16:03:40', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '2a81bc60-19ff-44ca-aff3-495492261cdf'	System	13 Sep 2020 21:04:18
User entered 'None (0)'	System	13 Sep 2020 21:04:18

FDA-CBER-2022-1614-3766580

US3862141
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 10:07:51
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-13T16:03:48', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '2a81bc60-19ff-44ca-aff3-495492261cdf'	System	13 Sep 2020 21:04:18
User entered 'None (0)'	System	13 Sep 2020 21:04:18

FDA-CBER-2022-1614-3766581

US3862141
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 10:07:51
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-13T16:03:54', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '2a81bc60-19ff-44ca-aff3-495492261cdf'	System	13 Sep 2020 21:04:18
User entered 'None (0)'	System	13 Sep 2020 21:04:18

FDA-CBER-2022-1614-3766582

US3862141
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 10:07:51
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-13T16:03:57', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '2a81bc60-19ff-44ca-aff3-495492261cdf'	System	13 Sep 2020 21:04:18
User entered 'None (0)'	System	13 Sep 2020 21:04:18

FDA-CBER-2022-1614-3766583

US3862141
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 10:07:51
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-13T16:04:00', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '2a81bc60-19ff-44ca-aff3-495492261cdf'	System	13 Sep 2020 21:04:18
User entered 'None (0)'	System	13 Sep 2020 21:04:18

FDA-CBER-2022-1614-3766584

US3862141
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 10:07:51
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-13T16:04:03', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '2a81bc60-19ff-44ca-aff3-495492261cdf'	System	13 Sep 2020 21:04:18
User entered 'None (0)'	System	13 Sep 2020 21:04:18

FDA-CBER-2022-1614-3766585

US3862141
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 10:07:51
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)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-13T16:04:08', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '2a81bc60-19ff-44ca-aff3-495492261cdf'	System	13 Sep 2020 21:04:18
User entered 'No (N)'	System	13 Sep 2020 21:04:18

FDA-CBER-2022-1614-3766586

US3862141
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 10:07:51
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-13T16:04:13', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '2a81bc60-19ff-44ca-aff3-495492261cdf'	System	13 Sep 2020 21:04:18
User entered '13 Sep 2020 16:04'	System	13 Sep 2020 21:04:18

FDA-CBER-2022-1614-3766587

US3862141
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 10:07:51
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 17:55:18

FDA-CBER-2022-1614-3766588

US3862141
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 10:07:51
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 17:55:18

FDA-CBER-2022-1614-3766589

US3862141
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 10:07:51
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
Data entry locked.	System	08 Sep 2020 17:55:18
User entered 'Day 7'	System	08 Sep 2020 17:55:18

US3862141
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 10:07:51
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-14T12:52:14', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '59704432-7aad-4726-9b97-e56b877c9c18'	System	14 Sep 2020 17:52:42
User entered 'None (0)'	System	14 Sep 2020 17:52:42

FDA-CBER-2022-1614-3766591

US3862141
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 10:07:51
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-14T12:52:17', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '59704432-7aad-4726-9b97-e56b877c9c18'	System	14 Sep 2020 17:52:42
User entered 'None (0)'	System	14 Sep 2020 17:52:42

FDA-CBER-2022-1614-3766592

US3862141
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 10:07:51
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-14T12:52:20', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '59704432-7aad-4726-9b97-e56b877c9c18'	System	14 Sep 2020 17:52:42
User entered 'None (0)'	System	14 Sep 2020 17:52:42

FDA-CBER-2022-1614-3766593

US3862141
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 10:07:51
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-14T12:52:23', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '59704432-7aad-4726-9b97-e56b877c9c18'	System	14 Sep 2020 17:52:42
User entered 'None (0)'	System	14 Sep 2020 17:52:42

FDA-CBER-2022-1614-3766594

US3862141
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 10:07:51
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-14T12:52:26', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '59704432-7aad-4726-9b97-e56b877c9c18'	System	14 Sep 2020 17:52:42
User entered 'None (0)'	System	14 Sep 2020 17:52:42

FDA-CBER-2022-1614-3766595

US3862141
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 10:07:51
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-14T12:52:29', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '59704432-7aad-4726-9b97-e56b877c9c18'	System	14 Sep 2020 17:52:42
User entered 'None (0)'	System	14 Sep 2020 17:52:42

FDA-CBER-2022-1614-3766596

US3862141
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 10:07:51
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)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-14T12:52:34', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '59704432-7aad-4726-9b97-e56b877c9c18'	System	14 Sep 2020 17:52:42
User entered 'No (N)'	System	14 Sep 2020 17:52:42

FDA-CBER-2022-1614-3766597

US3862141
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 10:07:51
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-09-14T12:52:39', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '59704432-7aad-4726-9b97-e56b877c9c18'	System	14 Sep 2020 17:52:42
User entered '14 Sep 2020 12:52'	System	14 Sep 2020 17:52:42

FDA-CBER-2022-1614-3766598

US3862141
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 10:07:51
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 17:55:18

FDA-CBER-2022-1614-3766599

US3862141
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 10:07:51
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 17:55:18

US3862141
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 10 Jun 2021 10:07:51
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered 'Yes (Y)'	Sandra Francisco (b) (4) (b) (4)	15 Sep 2020 22:23:00

US3862141
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 10 Jun 2021 10:07:51
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered '15 Sep 2020'	Sandra Francisco (b) (4) (b) (4)	15 Sep 2020 22:23:00

US3862141
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 10 Jun 2021 10:07:51
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered 'Contact Made (CONTACT MADE)'	Sandra Francisco (b) (4) (b) (4)	15 Sep 2020 22:23:00

US3862141
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 10 Jun 2021 10:07:51
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:49:55
User entered empty.	(b) (4) Sandra Francisco (b) (4) (b) (4)	15 Sep 2020 22:23:00

FDA-CBER-2022-1614-3766604

US3862141
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 10 Jun 2021 10:07:51
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered 'Yes (Y)'	Chanei Henry (b) (4) (b) (4)	22 Sep 2020 19:43:49

US3862141
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 10 Jun 2021 10:07:51
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User entered '1'	System	22 Sep 2020 19:43:49

FDA-CBER-2022-1614-3766606

US3862141
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 10 Jun 2021 10:07:51
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered 'Yes (Y)'	Chanei Henry (b) (4) (b) (4)	22 Sep 2020 19:43:58

US3862141
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 10 Jun 2021 10:07:51
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered '22 Sep 2020'	Chanei Henry (b) (4) (b) (4)	22 Sep 2020 19:43:58

US3862141
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 10 Jun 2021 10:07:51
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered 'Contact Made (CONTACT MADE)'	Chanei Henry (b) (4) (b) (4)	22 Sep 2020 19:43:58

US3862141
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 10 Jun 2021 10:07:51
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered empty.	Chanei Henry (b) (4) (b) (4)	22 Sep 2020 19:43:58

FDA-CBER-2022-1614-3766610

US3862141
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 10 Jun 2021 10:07:51
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered 'Yes (Y)'	Chanei Henry (b) (4) (b) (4)	22 Sep 2020 19:44:04

US3862141
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 10 Jun 2021 10:07:51
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User entered '1'	System	22 Sep 2020 19:44:04

FDA-CBER-2022-1614-3766612

US3862141
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 10 Jun 2021 10:07:51
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered 'Yes (Y)'	Sandra Francisco (b) (4) (b) (4)	30 Sep 2020 20:57:20

FDA-CBER-2022-1614-3766613

US3862141
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 10 Jun 2021 10:07:51
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered '29 Sep 2020'	Sandra Francisco (b) (4) (b) (4)	30 Sep 2020 20:57:20

US3862141
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 10 Jun 2021 10:07:51
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered 'Contact Made (CONTACT MADE)'	Sandra Francisco (b) (4) (b) (4)	30 Sep 2020 20:57:20

US3862141
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 10 Jun 2021 10:07:51
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:49:55
User entered empty.	(b) (4) Sandra Francisco (b) (4) (b) (4)	30 Sep 2020 20:57:20

FDA-CBER-2022-1614-3766616

US3862141
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 10 Jun 2021 10:07:51
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered 'Yes (Y)'	Carrie Kibler (b) (4) (b) (4)	06 Oct 2020 17:21:31

US3862141
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 10 Jun 2021 10:07:51
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User entered '1'	System	06 Oct 2020 17:21:31

FDA-CBER-2022-1614-3766618

US3862141
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 10 Jun 2021 10:07:51
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:25
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered 'Yes (Y)'	Carrie Kibler (b) (4) (b) (4)	06 Oct 2020 17:21:45

FDA-CBER-2022-1614-3766619

US3862141
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 10 Jun 2021 10:07:51
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:25
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered '6 Oct 2020'	Carrie Kibler (b) (4) (b) (4)	06 Oct 2020 17:21:45

FDA-CBER-2022-1614-3766620

US3862141
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 10 Jun 2021 10:07:51
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:25
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered 'Clinic (Clinic)'	Carrie Kibler (b) (4) (b) (4)	06 Oct 2020 17:21:45

US3862141
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 10 Jun 2021 10:07:51
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:25
User entered 'VISIT2'	System	06 Oct 2020 17:21:45

FDA-CBER-2022-1614-3766622

US3862141
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 10:07:51
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:25
User accepted default value 'Pre-Dose (PREDOSE)'	Trent Davis (b) (4) (b) (4)	06 Oct 2020 20:53:40

US3862141
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 10:07:51
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:25
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered 'Yes (Y)'	Trent Davis (b) (4) (b) (4)	06 Oct 2020 20:53:40

FDA-CBER-2022-1614-3766624

US3862141
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 10:07:51
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:25
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered '6 Oct 2020'	Trent Davis (b) (4) (b) (4)	06 Oct 2020 20:53:40

US3862141
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 10:07:51
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:25
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered '11:15'	Trent Davis (b) (4) (b) (4)	06 Oct 2020 20:53:40

US3862141
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 10:07:51
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:25
User entered '6 Oct 2020 11:15'	System	06 Oct 2020 20:53:40

FDA-CBER-2022-1614-3766627

US3862141
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 10:07:51
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:25
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered '098.3' F	Trent Davis (b) (4) (b) (4)	06 Oct 2020 20:53:40

US3862141
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 10:07:51
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:25
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered 'Other (Other)'	Trent Davis (b) (4) (b) (4)	06 Oct 2020 20:53:40

US3862141
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 10:07:51
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:25
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered 'temporal'	Trent Davis (b) (4) (b) (4)	06 Oct 2020 20:53:40

US3862141
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 10:07:51
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:25
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered '065'	Trent Davis (b) (4) (b) (4)	06 Oct 2020 20:53:40

FDA-CBER-2022-1614-3766631

US3862141
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 10:07:51
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:25
User entered 'bpm'	System	06 Oct 2020 20:53:40

FDA-CBER-2022-1614-3766632

US3862141
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 10:07:51
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:25
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered '018'	Trent Davis (b) (4) (b) (4)	06 Oct 2020 20:53:40

US3862141
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 10:07:51
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:25
User entered 'breaths/min'	System	06 Oct 2020 20:53:40

FDA-CBER-2022-1614-3766634

US3862141
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 10:07:51
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:25
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered '145'	Trent Davis (b) (4) (b) (4)	06 Oct 2020 20:53:40

FDA-CBER-2022-1614-3766635

US3862141
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 10:07:51
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:25
User entered 'mmHg'	System	06 Oct 2020 20:53:40

FDA-CBER-2022-1614-3766636

US3862141
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 10:07:51
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:25
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered '072'	Trent Davis (b) (4) (b) (4)	06 Oct 2020 20:53:40

FDA-CBER-2022-1614-3766637

US3862141
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 10:07:51
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:25
User entered 'mmHg'	System	06 Oct 2020 20:53:40

FDA-CBER-2022-1614-3766638

US3862141
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 10:07:51
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:25
User accepted default value 'Post-Dose (POSTDOSE)'	Trent Davis (b) (4) (b) (4)	06 Oct 2020 20:53:40

FDA-CBER-2022-1614-3766639

US3862141
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 10:07:51
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:25
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered 'Yes (Y)'	Trent Davis (b) (4) (b) (4)	06 Oct 2020 20:53:40

FDA-CBER-2022-1614-3766640

US3862141
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 10:07:51
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:25
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered '6 Oct 2020'	Trent Davis (b) (4) (b) (4)	06 Oct 2020 20:53:40

FDA-CBER-2022-1614-3766641

US3862141
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 10:07:51
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:25
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered '13:22'	Trent Davis (b) (4) (b) (4)	06 Oct 2020 20:53:40

FDA-CBER-2022-1614-3766642

US3862141
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 10:07:51
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:25
User entered '6 Oct 2020 13:22'	System	06 Oct 2020 20:53:40

FDA-CBER-2022-1614-3766643

US3862141
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 10:07:51
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:25
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered '097.8' F	Trent Davis (b) (4) (b) (4)	06 Oct 2020 20:53:40

FDA-CBER-2022-1614-3766644

US3862141
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 10:07:51
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:25
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered 'Other (Other)'	Trent Davis (b) (4) (b) (4)	06 Oct 2020 20:53:40

US3862141
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 10:07:51
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:25
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered 'temporal'	Trent Davis (b) (4) (b) (4)	06 Oct 2020 20:53:40

US3862141
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 10:07:51
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:25
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered '064'	Trent Davis (b) (4) (b) (4)	06 Oct 2020 20:53:40

FDA-CBER-2022-1614-3766647

US3862141
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 10:07:51
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:25
User entered 'bpm'	System	06 Oct 2020 20:53:40

FDA-CBER-2022-1614-3766648

US3862141
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 10:07:51
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:25
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered '018'	Trent Davis (b) (4) (b) (4)	06 Oct 2020 20:53:40

US3862141
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 10:07:51
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:25
User entered 'breaths/min'	System	06 Oct 2020 20:53:40

US3862141
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 10:07:51
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:25
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered '137'	Trent Davis (b) (4) (b) (4)	06 Oct 2020 20:53:40

US3862141
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 10:07:51
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:25
User entered 'mmHg'	System	06 Oct 2020 20:53:40

FDA-CBER-2022-1614-3766652

US3862141
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 10:07:51
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:25
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered '063'	Trent Davis (b) (4) (b) (4)	06 Oct 2020 20:53:40

US3862141
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 10:07:51
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:25
User entered 'mmHg'	System	06 Oct 2020 20:53:40

FDA-CBER-2022-1614-3766654

US3862141
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Generated On: 10 Jun 2021 10:07:51
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered 'Yes (Y)'	Carrie Kibler (b) (4) (b) (4)	06 Oct 2020 17:23:31

FDA-CBER-2022-1614-3766655

US3862141
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Generated On: 10 Jun 2021 10:07:51
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered '6 Oct 2020'	Carrie Kibler (b) (4) (b) (4)	06 Oct 2020 17:23:31

FDA-CBER-2022-1614-3766656

US3862141
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 10:07:51
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered 'Yes (Y)'	Sandra Francisco (b) (4) (b) (4)	06 Oct 2020 17:40:54

FDA-CBER-2022-1614-3766657

US3862141
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 10:07:51
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered empty.	Sandra Francisco (b) (4) (b) (4)	06 Oct 2020 17:40:54

US3862141
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 10:07:51

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered empty.	Sandra Francisco (b) (4) (b) (4)	06 Oct 2020 17:40:54

US3862141
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 10:07:51
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User entered 'MRNA-1273 OR PLACEBO'	System	06 Oct 2020 17:40:54

FDA-CBER-2022-1614-3766660

US3862141
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 10:07:51
What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered '6 Oct 2020'	Sandra Francisco (b) (4) (b) (4)	06 Oct 2020 17:40:54

US3862141
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 10:07:51
What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered '12:37'	Sandra Francisco (b) (4) (b) (4)	06 Oct 2020 17:40:54

FDA-CBER-2022-1614-3766662

US3862141
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 10:07:51
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User entered '6 Oct 2020 12:37'	System	06 Oct 2020 17:40:54

FDA-CBER-2022-1614-3766663

US3862141
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 10:07:51
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered 'Left Arm (LEFT ARM)'	Sandra Francisco (b) (4) (b) (4)	06 Oct 2020 17:40:54

US3862141
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 10:07:51
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User entered 'ONCE'	System	06 Oct 2020 17:40:54

US3862141
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 10:07:51
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User entered 'INTRAMUSCULAR'	System	06 Oct 2020 17:40:54

US3862141
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 10:07:51
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered 'Yes (Y)'	Trent Davis (b) (4) (b) (4)	06 Oct 2020 20:54:03

FDA-CBER-2022-1614-3766667

US3862141
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 10:07:51
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered '6 Oct 2020'	Trent Davis (b) (4) (b) (4)	06 Oct 2020 20:54:03

FDA-CBER-2022-1614-3766668

US3862141
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 10:07:51
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered '12:00'	Trent Davis (b) (4) (b) (4)	06 Oct 2020 20:54:03

US3862141
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 10:07:51
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User entered '6 Oct 2020 12:00'	System	06 Oct 2020 20:54:03

US3862141
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab
Generated On: 10 Jun 2021 10:07:51
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered '6 Oct 2020'	Trent Davis (b) (4) (b) (4)	06 Oct 2020 20:54:18

US3862141
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 10:07:51
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Trent Davis (b) (4) (b) (4)	06 Oct 2020 20:54:18

US3862141
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 10:07:51
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered 'No (N)'	Trent Davis (b) (4) (b) (4)	06 Oct 2020 20:54:18

FDA-CBER-2022-1614-3766673

US3862141
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 10:07:51
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered empty.	Trent Davis (b) (4) (b) (4)	06 Oct 2020 20:54:18

US3862141
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 10:07:51
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User entered empty.	System	06 Oct 2020 20:54:18

FDA-CBER-2022-1614-3766675

US3862141
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 10:07:51
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Trent Davis (b) (4) (b) (4)	06 Oct 2020 20:54:18

US3862141
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 10:07:51
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered 'Yes (Y)'	Trent Davis (b) (4) (b) (4)	06 Oct 2020 20:54:18

US3862141
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 10:07:51
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered '11:52'	Trent Davis (b) (4) (b) (4)	06 Oct 2020 20:54:18

US3862141
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 10:07:51
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User entered '6 Oct 2020 11:52'	System	06 Oct 2020 20:54:18

FDA-CBER-2022-1614-3766679

US3862141
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 10 Jun 2021 10:07:51
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered 'Yes (Y)'	Carrie Kibler (b) (4) (b) (4)	06 Oct 2020 17:23:55

FDA-CBER-2022-1614-3766680

US3862141
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 10 Jun 2021 10:07:51
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User entered '1'	System	06 Oct 2020 17:23:55

FDA-CBER-2022-1614-3766681

US3862141
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 10:07:51
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
Data entry locked.	System	06 Oct 2020 17:40:54
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Oct 2020 17:40:54

US3862141
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 10:07:51
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-06T13:05:04', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '1032e5ef-203b-496a-835c-f2479993bc09'	System	06 Oct 2020 18:05:48
User entered 'Yes (Y)'	System	06 Oct 2020 18:05:48

FDA-CBER-2022-1614-3766683

US3862141
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 10:07:51
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-06T13:05:12', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '1032e5ef-203b-496a-835c-f2479993bc09'	System	06 Oct 2020 18:05:48
User entered '98.2'	System	06 Oct 2020 18:05:48

FDA-CBER-2022-1614-3766684

US3862141
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 10:07:51
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-06T13:05:17', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '1032e5ef-203b-496a-835c-f2479993bc09'	System	06 Oct 2020 18:05:48
User entered 'No (N)'	System	06 Oct 2020 18:05:48

FDA-CBER-2022-1614-3766685

US3862141
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 10:07:51
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-06T13:05:44', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '1032e5ef-203b-496a-835c-f2479993bc09'	System	06 Oct 2020 18:05:48
User entered '06 Oct 2020 13:05'	System	06 Oct 2020 18:05:48

FDA-CBER-2022-1614-3766686

US3862141
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 10:07:51
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
User entered '06 Oct 2020 12:57'	System	06 Oct 2020 17:40:54

FDA-CBER-2022-1614-3766687

US3862141
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 10:07:51
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
User entered '06 Oct 2020 15:27'	System	06 Oct 2020 17:40:54

FDA-CBER-2022-1614-3766688

US3862141
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 10:07:51
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
Data entry locked.	System	06 Oct 2020 17:40:54
User entered 'Day 1, after vaccination (at home)'	System	06 Oct 2020 17:40:54

US3862141
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 10:07:51
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-06T18:47:11', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '71373f25-29be-4cc8-b983-f2b832c5d121'	System	06 Oct 2020 23:47:37
User entered 'Yes (Y)'	System	06 Oct 2020 23:47:37

FDA-CBER-2022-1614-3766690

US3862141
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 10:07:51
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-06T18:47:20', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '71373f25-29be-4cc8-b983-f2b832c5d121'	System	06 Oct 2020 23:47:37
User entered '98.5'	System	06 Oct 2020 23:47:37

FDA-CBER-2022-1614-3766691

US3862141
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 10:07:51
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-06T18:47:25', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '71373f25-29be-4cc8-b983-f2b832c5d121'	System	06 Oct 2020 23:47:37
User entered 'No (N)'	System	06 Oct 2020 23:47:37

FDA-CBER-2022-1614-3766692

US3862141
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 10:07:51
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-06T18:47:33', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '71373f25-29be-4cc8-b983-f2b832c5d121'	System	06 Oct 2020 23:47:37
User entered '06 Oct 2020 18:47'	System	06 Oct 2020 23:47:37

FDA-CBER-2022-1614-3766693

US3862141
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 10:07:51
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
User entered '06 Oct 2020 16:22'	System	06 Oct 2020 17:40:54

FDA-CBER-2022-1614-3766694

US3862141
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 10:07:51
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
User entered '07 Oct 2020 11:59'	System	06 Oct 2020 17:40:54

FDA-CBER-2022-1614-3766695

US3862141
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 10:07:51
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
Data entry locked.	System	06 Oct 2020 17:40:54
User entered 'Day 2'	System	06 Oct 2020 17:40:54

FDA-CBER-2022-1614-3766696

US3862141
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 10:07:51
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-07T12:21:39', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '1ec00727-8c5d-4b2f-a035-d5010ce0ebc9'	System	07 Oct 2020 17:22:11
User entered 'Yes (Y)'	System	07 Oct 2020 17:22:11

FDA-CBER-2022-1614-3766697

US3862141
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 10:07:51
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-07T12:21:55', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '1ec00727-8c5d-4b2f-a035-d5010ce0ebc9'	System	07 Oct 2020 17:22:11
User entered '98.3'	System	07 Oct 2020 17:22:11

FDA-CBER-2022-1614-3766698

US3862141
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 10:07:51
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-07T12:22:00', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '1ec00727-8c5d-4b2f-a035-d5010ce0ebc9'	System	07 Oct 2020 17:22:11
User entered 'No (N)'	System	07 Oct 2020 17:22:11

US3862141
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 10:07:51
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-07T12:22:08', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '1ec00727-8c5d-4b2f-a035-d5010ce0ebc9'	System	07 Oct 2020 17:22:11
User entered '07 Oct 2020 12:22'	System	07 Oct 2020 17:22:11

FDA-CBER-2022-1614-3766700

US3862141
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 10:07:51
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
User entered '07 Oct 2020 12:00'	System	06 Oct 2020 17:40:54

FDA-CBER-2022-1614-3766701

US3862141
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 10:07:51
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
User entered '08 Oct 2020 11:59'	System	06 Oct 2020 17:40:54

FDA-CBER-2022-1614-3766702

US3862141
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 10:07:51
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
Data entry locked.	System	06 Oct 2020 17:40:54
User entered 'Day 3'	System	06 Oct 2020 17:40:54

US3862141
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 10:07:51
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-08T12:02:31', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'ae8ecf65-62f2-4d26-93ee-f48c353a0359'	System	08 Oct 2020 17:03:49
User entered 'Yes (Y)'	System	08 Oct 2020 17:03:49

FDA-CBER-2022-1614-3766704

US3862141
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 10:07:51
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-08T12:02:42', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'ae8ecf65-62f2-4d26-93ee-f48c353a0359'	System	08 Oct 2020 17:03:49
User entered '97.7'	System	08 Oct 2020 17:03:49

FDA-CBER-2022-1614-3766705

US3862141
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 10:07:51
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-08T12:02:49', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'ae8ecf65-62f2-4d26-93ee-f48c353a0359'	System	08 Oct 2020 17:03:49
User entered 'Yes (Y)'	System	08 Oct 2020 17:03:49

FDA-CBER-2022-1614-3766706

US3862141
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 10:07:51
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).		03 Dec 2020 09:19:32
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'medication documented' (Site from System).	Chanei Henry (b) (4) (b) (4)	01 Dec 2020 17:41:46
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	08 Oct 2020 17:03:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-08T12:03:10', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'ae8ecf65-62f2-4d26-93ee-f48c353a0359'	System	08 Oct 2020 17:03:49
User entered '1'	System	08 Oct 2020 17:03:49

FDA-CBER-2022-1614-3766707

US3862141
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 10:07:51
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-08T12:03:10', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'ae8ecf65-62f2-4d26-93ee-f48c353a0359'	System	08 Oct 2020 17:03:49
User entered '0'	System	08 Oct 2020 17:03:49

FDA-CBER-2022-1614-3766708

US3862141
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 10:07:51
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-08T12:03:25', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'ae8ecf65-62f2-4d26-93ee-f48c353a0359'	System	08 Oct 2020 17:03:49
User entered '08 Oct 2020 12:03'	System	08 Oct 2020 17:03:49

FDA-CBER-2022-1614-3766709

US3862141
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 10:07:51
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
User entered '08 Oct 2020 12:00'	System	06 Oct 2020 17:40:54

FDA-CBER-2022-1614-3766710

US3862141
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 10:07:51
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
User entered '09 Oct 2020 11:59'	System	06 Oct 2020 17:40:54

FDA-CBER-2022-1614-3766711

US3862141
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 10:07:51
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
Data entry locked.	System	06 Oct 2020 17:40:54
User entered 'Day 4'	System	06 Oct 2020 17:40:54

US3862141
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 10:07:51
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-09T13:50:01', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'd0b0716e-ff63-45a3-9c13-4a89d7621391'	System	09 Oct 2020 18:50:22
User entered 'Yes (Y)'	System	09 Oct 2020 18:50:22

FDA-CBER-2022-1614-3766713

US3862141
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 10:07:51
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-09T13:50:11', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'd0b0716e-ff63-45a3-9c13-4a89d7621391'	System	09 Oct 2020 18:50:22
User entered '98.2'	System	09 Oct 2020 18:50:22

FDA-CBER-2022-1614-3766714

US3862141
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 10:07:51
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-09T13:50:15', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'd0b0716e-ff63-45a3-9c13-4a89d7621391'	System	09 Oct 2020 18:50:22
User entered 'No (N)'	System	09 Oct 2020 18:50:22

FDA-CBER-2022-1614-3766715

US3862141
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 10:07:51
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-09T13:50:20', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'd0b0716e-ff63-45a3-9c13-4a89d7621391'	System	09 Oct 2020 18:50:22
User entered '09 Oct 2020 13:50'	System	09 Oct 2020 18:50:22

FDA-CBER-2022-1614-3766716

US3862141
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 10:07:51
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
User entered '09 Oct 2020 12:00'	System	06 Oct 2020 17:40:54

FDA-CBER-2022-1614-3766717

US3862141
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 10:07:51
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
User entered '10 Oct 2020 11:59'	System	06 Oct 2020 17:40:54

FDA-CBER-2022-1614-3766718

US3862141
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 10:07:51
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
Data entry locked.	System	06 Oct 2020 17:40:54
User entered 'Day 5'	System	06 Oct 2020 17:40:54

FDA-CBER-2022-1614-3766719

US3862141
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 10:07:51
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-10T12:41:10', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'bcf6366d-7437-448f-835d-4bbcfe03ad32'	System	10 Oct 2020 17:41:30
User entered 'Yes (Y)'	System	10 Oct 2020 17:41:30

FDA-CBER-2022-1614-3766720

US3862141
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 10:07:51
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-10T12:41:17', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'bcf6366d-7437-448f-835d-4bbcfe03ad32'	System	10 Oct 2020 17:41:30
User entered '98.4'	System	10 Oct 2020 17:41:30

FDA-CBER-2022-1614-3766721

US3862141
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 10:07:51
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-10T12:41:21', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'bcf6366d-7437-448f-835d-4bbcfe03ad32'	System	10 Oct 2020 17:41:30
User entered 'No (N)'	System	10 Oct 2020 17:41:30

FDA-CBER-2022-1614-3766722

US3862141
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 10:07:51
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-10T12:41:25', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'bcf6366d-7437-448f-835d-4bbcfe03ad32'	System	10 Oct 2020 17:41:30
User entered '10 Oct 2020 12:41'	System	10 Oct 2020 17:41:30

FDA-CBER-2022-1614-3766723

US3862141
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 10:07:51
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
User entered '10 Oct 2020 12:00'	System	06 Oct 2020 17:40:54

FDA-CBER-2022-1614-3766724

US3862141
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 10:07:51
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
User entered '11 Oct 2020 11:59'	System	06 Oct 2020 17:40:54

FDA-CBER-2022-1614-3766725

US3862141
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 10:07:51
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
Data entry locked.	System	06 Oct 2020 17:40:54
User entered 'Day 6'	System	06 Oct 2020 17:40:54

FDA-CBER-2022-1614-3766726

US3862141
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 10:07:51
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-11T13:35:50', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '8698c66c-56f9-4344-a057-2e49b70bf46d'	System	11 Oct 2020 18:36:16
User entered 'Yes (Y)'	System	11 Oct 2020 18:36:16

FDA-CBER-2022-1614-3766727

US3862141
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 10:07:51
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-11T13:36:05', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '8698c66c-56f9-4344-a057-2e49b70bf46d'	System	11 Oct 2020 18:36:16
User entered '97.4'	System	11 Oct 2020 18:36:16

FDA-CBER-2022-1614-3766728

US3862141
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 10:07:51
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-11T13:36:09', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '8698c66c-56f9-4344-a057-2e49b70bf46d'	System	11 Oct 2020 18:36:16
User entered 'No (N)'	System	11 Oct 2020 18:36:16

FDA-CBER-2022-1614-3766729

US3862141
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 10:07:51
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-11T13:36:14', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '8698c66c-56f9-4344-a057-2e49b70bf46d'	System	11 Oct 2020 18:36:16
User entered '11 Oct 2020 13:36'	System	11 Oct 2020 18:36:16

US3862141
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 10:07:51
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
User entered '11 Oct 2020 12:00'	System	06 Oct 2020 17:40:54

FDA-CBER-2022-1614-3766731

US3862141
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 10:07:51
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
User entered '12 Oct 2020 11:59'	System	06 Oct 2020 17:40:54

FDA-CBER-2022-1614-3766732

US3862141
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 10:07:51
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
Data entry locked.	System	06 Oct 2020 17:40:54
User entered 'Day 7'	System	06 Oct 2020 17:40:54

FDA-CBER-2022-1614-3766733

US3862141
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 10:07:51
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-12T12:23:50', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '76f76a5c-008b-4e72-9e1e-dd2091ddd747'	System	12 Oct 2020 17:24:09
User entered 'Yes (Y)'	System	12 Oct 2020 17:24:09

FDA-CBER-2022-1614-3766734

US3862141
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 10:07:51
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-12T12:23:57', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '76f76a5c-008b-4e72-9e1e-dd2091ddd747'	System	12 Oct 2020 17:24:09
User entered '97.2'	System	12 Oct 2020 17:24:09

FDA-CBER-2022-1614-3766735

US3862141
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 10:07:51
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-12T12:24:02', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '76f76a5c-008b-4e72-9e1e-dd2091ddd747'	System	12 Oct 2020 17:24:09
User entered 'No (N)'	System	12 Oct 2020 17:24:09

FDA-CBER-2022-1614-3766736

US3862141
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 10:07:51
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-12T12:24:07', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '76f76a5c-008b-4e72-9e1e-dd2091ddd747'	System	12 Oct 2020 17:24:09
User entered '12 Oct 2020 12:24'	System	12 Oct 2020 17:24:09

FDA-CBER-2022-1614-3766737

US3862141
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 10:07:51
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
User entered '12 Oct 2020 12:00'	System	06 Oct 2020 17:40:54

FDA-CBER-2022-1614-3766738

US3862141
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 10:07:51
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
User entered '13 Oct 2020 11:59'	System	06 Oct 2020 17:40:54

FDA-CBER-2022-1614-3766739

US3862141
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 10:07:51
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
Data entry locked.	System	06 Oct 2020 17:40:54
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Oct 2020 17:40:54

US3862141
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 10:07:51
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-06T13:26:51', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '683e2e81-861f-47f4-8f4f-5055dd109caf'	System	06 Oct 2020 18:27:20
User entered 'None (1)'	System	06 Oct 2020 18:27:20

FDA-CBER-2022-1614-3766741

US3862141
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 10:07:51
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-06T13:26:57', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '683e2e81-861f-47f4-8f4f-5055dd109caf'	System	06 Oct 2020 18:27:20
User entered 'No (N)'	System	06 Oct 2020 18:27:20

US3862141
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 10:07:51
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-06T13:27:03', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '683e2e81-861f-47f4-8f4f-5055dd109caf'	System	06 Oct 2020 18:27:20
User entered 'No (N)'	System	06 Oct 2020 18:27:20

FDA-CBER-2022-1614-3766743

US3862141
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 10:07:51
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-06T13:27:10', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '683e2e81-861f-47f4-8f4f-5055dd109caf'	System	06 Oct 2020 18:27:20
User entered 'None (1)'	System	06 Oct 2020 18:27:20

FDA-CBER-2022-1614-3766744

US3862141
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 10:07:51
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-06T13:27:16', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '683e2e81-861f-47f4-8f4f-5055dd109caf'	System	06 Oct 2020 18:27:20
User entered '06 Oct 2020 13:27'	System	06 Oct 2020 18:27:20

FDA-CBER-2022-1614-3766745

US3862141
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 10:07:51
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
User entered '06 Oct 2020 12:57'	System	06 Oct 2020 17:40:54

FDA-CBER-2022-1614-3766746

US3862141
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 10:07:51
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
User entered '06 Oct 2020 15:27'	System	06 Oct 2020 17:40:54

FDA-CBER-2022-1614-3766747

US3862141
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 10:07:51
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
Data entry locked.	System	06 Oct 2020 17:40:54
User entered 'Day 1, after vaccination (at home)'	System	06 Oct 2020 17:40:54

US3862141
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 10:07:51
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-06T18:47:53', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '5628b110-b5d4-4687-9ce9-e81b6e47c160'	System	06 Oct 2020 23:48:29
User entered 'None (1)'	System	06 Oct 2020 23:48:29

FDA-CBER-2022-1614-3766749

US3862141
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 10:07:51
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-06T18:48:11', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '5628b110-b5d4-4687-9ce9-e81b6e47c160'	System	06 Oct 2020 23:48:29
User entered 'No (N)'	System	06 Oct 2020 23:48:29

FDA-CBER-2022-1614-3766750

US3862141
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 10:07:51
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-06T18:48:15', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '5628b110-b5d4-4687-9ce9-e81b6e47c160'	System	06 Oct 2020 23:48:29
User entered 'No (N)'	System	06 Oct 2020 23:48:29

US3862141
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 10:07:51
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-06T18:48:20', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '5628b110-b5d4-4687-9ce9-e81b6e47c160'	System	06 Oct 2020 23:48:29
User entered 'None (1)'	System	06 Oct 2020 23:48:29

FDA-CBER-2022-1614-3766752

US3862141
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 10:07:51
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-06T18:48:27', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '5628b110-b5d4-4687-9ce9-e81b6e47c160'	System	06 Oct 2020 23:48:29
User entered '06 Oct 2020 18:48'	System	06 Oct 2020 23:48:29

FDA-CBER-2022-1614-3766753

US3862141
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 10:07:51
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
User entered '06 Oct 2020 16:22'	System	06 Oct 2020 17:40:54

FDA-CBER-2022-1614-3766754

US3862141
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 10:07:51
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
User entered '07 Oct 2020 11:59'	System	06 Oct 2020 17:40:54

FDA-CBER-2022-1614-3766755

US3862141
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 10:07:51
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
Data entry locked.	System	06 Oct 2020 17:40:54
User entered 'Day 2'	System	06 Oct 2020 17:40:54

FDA-CBER-2022-1614-3766756

US3862141
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 10:07:51
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-07T12:22:38', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '994b95a4-a37f-4fe0-a203-56b0c6b4e457'	System	07 Oct 2020 17:23:10
User entered 'Does not interfere with activity (2)'	System	07 Oct 2020 17:23:10

FDA-CBER-2022-1614-3766757

US3862141
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 10:07:51
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-07T12:22:44', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '994b95a4-a37f-4fe0-a203-56b0c6b4e457'	System	07 Oct 2020 17:23:10
User entered 'No (N)'	System	07 Oct 2020 17:23:10

US3862141
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 10:07:51
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-07T12:22:50', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '994b95a4-a37f-4fe0-a203-56b0c6b4e457'	System	07 Oct 2020 17:23:10
User entered 'No (N)'	System	07 Oct 2020 17:23:10

FDA-CBER-2022-1614-3766759

US3862141
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 10:07:51
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-07T12:22:55', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '994b95a4-a37f-4fe0-a203-56b0c6b4e457'	System	07 Oct 2020 17:23:10
User entered 'None (1)'	System	07 Oct 2020 17:23:10

US3862141
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 10:07:51
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-07T12:23:05', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '994b95a4-a37f-4fe0-a203-56b0c6b4e457'	System	07 Oct 2020 17:23:10
User entered '07 Oct 2020 12:23'	System	07 Oct 2020 17:23:10

FDA-CBER-2022-1614-3766761

US3862141
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 10:07:51
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
User entered '07 Oct 2020 12:00'	System	06 Oct 2020 17:40:54

FDA-CBER-2022-1614-3766762

US3862141
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 10:07:51
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
User entered '08 Oct 2020 11:59'	System	06 Oct 2020 17:40:54

FDA-CBER-2022-1614-3766763

US3862141
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 10:07:51
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
Data entry locked.	System	06 Oct 2020 17:40:54
User entered 'Day 3'	System	06 Oct 2020 17:40:54

FDA-CBER-2022-1614-3766764

US3862141
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 10:07:51
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-08T12:03:40', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'fd29258d-6ad4-4f89-a469-d5d5516ffcae'	System	08 Oct 2020 17:04:09
User entered 'Does not interfere with activity (2)'	System	08 Oct 2020 17:04:09

FDA-CBER-2022-1614-3766765

US3862141
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 10:07:51
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-08T12:03:43', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'fd29258d-6ad4-4f89-a469-d5d5516ffcae'	System	08 Oct 2020 17:04:09
User entered 'No (N)'	System	08 Oct 2020 17:04:09

FDA-CBER-2022-1614-3766766

US3862141
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 10:07:51
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-08T12:03:46', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'fd29258d-6ad4-4f89-a469-d5d5516ffcae'	System	08 Oct 2020 17:04:09
User entered 'No (N)'	System	08 Oct 2020 17:04:09

FDA-CBER-2022-1614-3766767

US3862141
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 10:07:51
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-08T12:03:48', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'fd29258d-6ad4-4f89-a469-d5d5516ffcae'	System	08 Oct 2020 17:04:09
User entered 'None (1)'	System	08 Oct 2020 17:04:09

FDA-CBER-2022-1614-3766768

US3862141
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 10:07:51
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-08T12:03:52', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'fd29258d-6ad4-4f89-a469-d5d5516ffcae'	System	08 Oct 2020 17:04:09
User entered '08 Oct 2020 12:03'	System	08 Oct 2020 17:04:09

FDA-CBER-2022-1614-3766769

US3862141
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 10:07:51
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
User entered '08 Oct 2020 12:00'	System	06 Oct 2020 17:40:54

FDA-CBER-2022-1614-3766770

US3862141
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 10:07:51
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
User entered '09 Oct 2020 11:59'	System	06 Oct 2020 17:40:54

FDA-CBER-2022-1614-3766771

US3862141
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 10:07:51
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
Data entry locked.	System	06 Oct 2020 17:40:54
User entered 'Day 4'	System	06 Oct 2020 17:40:54

FDA-CBER-2022-1614-3766772

US3862141
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 10:07:51
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-09T13:50:29', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '50765dce-8689-4cc1-96f1-8aa039be9927'	System	09 Oct 2020 18:50:50
User entered 'None (1)'	System	09 Oct 2020 18:50:50

US3862141
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 10:07:51
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-09T13:50:33', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '50765dce-8689-4cc1-96f1-8aa039be9927'	System	09 Oct 2020 18:50:50
User entered 'No (N)'	System	09 Oct 2020 18:50:50

US3862141
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 10:07:51
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-09T13:50:36', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '50765dce-8689-4cc1-96f1-8aa039be9927'	System	09 Oct 2020 18:50:50
User entered 'No (N)'	System	09 Oct 2020 18:50:50

FDA-CBER-2022-1614-3766775

US3862141
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 10:07:51
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-09T13:50:39', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '50765dce-8689-4cc1-96f1-8aa039be9927'	System	09 Oct 2020 18:50:50
User entered 'None (1)'	System	09 Oct 2020 18:50:50

US3862141
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 10:07:51
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-09T13:50:47', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '50765dce-8689-4cc1-96f1-8aa039be9927'	System	09 Oct 2020 18:50:50
User entered '09 Oct 2020 13:50'	System	09 Oct 2020 18:50:50

FDA-CBER-2022-1614-3766777

US3862141
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 10:07:51
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
User entered '09 Oct 2020 12:00'	System	06 Oct 2020 17:40:54

FDA-CBER-2022-1614-3766778

US3862141
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 10:07:51
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
User entered '10 Oct 2020 11:59'	System	06 Oct 2020 17:40:54

FDA-CBER-2022-1614-3766779

US3862141
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 10:07:51
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
Data entry locked.	System	06 Oct 2020 17:40:54
User entered 'Day 5'	System	06 Oct 2020 17:40:54

FDA-CBER-2022-1614-3766780

US3862141
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 10:07:51
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-10T12:41:42', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '2812fc28-b183-44d4-8ed2-7e6ede32b23e'	System	10 Oct 2020 17:42:07
User entered 'None (1)'	System	10 Oct 2020 17:42:07

FDA-CBER-2022-1614-3766781

US3862141
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 10:07:51
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-10T12:41:46', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '2812fc28-b183-44d4-8ed2-7e6ede32b23e'	System	10 Oct 2020 17:42:07
User entered 'No (N)'	System	10 Oct 2020 17:42:07

US3862141
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 10:07:51
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-10T12:41:52', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '2812fc28-b183-44d4-8ed2-7e6ede32b23e'	System	10 Oct 2020 17:42:07
User entered 'No (N)'	System	10 Oct 2020 17:42:07

FDA-CBER-2022-1614-3766783

US3862141
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 10:07:51
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-10T12:41:55', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '2812fc28-b183-44d4-8ed2-7e6ede32b23e'	System	10 Oct 2020 17:42:07
User entered 'None (1)'	System	10 Oct 2020 17:42:07

FDA-CBER-2022-1614-3766784

US3862141
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 10:07:51
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-10T12:42:03', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '2812fc28-b183-44d4-8ed2-7e6ede32b23e'	System	10 Oct 2020 17:42:07
User entered '10 Oct 2020 12:42'	System	10 Oct 2020 17:42:07

FDA-CBER-2022-1614-3766785

US3862141
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 10:07:51
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
User entered '10 Oct 2020 12:00'	System	06 Oct 2020 17:40:54

FDA-CBER-2022-1614-3766786

US3862141
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 10:07:51
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
User entered '11 Oct 2020 11:59'	System	06 Oct 2020 17:40:54

FDA-CBER-2022-1614-3766787

US3862141
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 10:07:51
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
Data entry locked.	System	06 Oct 2020 17:40:54
User entered 'Day 6'	System	06 Oct 2020 17:40:54

FDA-CBER-2022-1614-3766788

US3862141
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 10:07:51
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-11T13:36:19', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'f5dea927-1f16-46df-a6b0-1a5f7540c838'	System	11 Oct 2020 18:36:37
User entered 'None (1)'	System	11 Oct 2020 18:36:37

FDA-CBER-2022-1614-3766789

US3862141
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 10:07:51
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-11T13:36:23', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'f5dea927-1f16-46df-a6b0-1a5f7540c838'	System	11 Oct 2020 18:36:37
User entered 'No (N)'	System	11 Oct 2020 18:36:37

US3862141
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 10:07:51
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-11T13:36:26', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'f5dea927-1f16-46df-a6b0-1a5f7540c838'	System	11 Oct 2020 18:36:37
User entered 'No (N)'	System	11 Oct 2020 18:36:37

US3862141
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 10:07:51
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-11T13:36:28', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'f5dea927-1f16-46df-a6b0-1a5f7540c838'	System	11 Oct 2020 18:36:37
User entered 'None (1)'	System	11 Oct 2020 18:36:37

FDA-CBER-2022-1614-3766792

US3862141
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 10:07:51
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-11T13:36:32', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'f5dea927-1f16-46df-a6b0-1a5f7540c838'	System	11 Oct 2020 18:36:37
User entered '11 Oct 2020 13:36'	System	11 Oct 2020 18:36:37

FDA-CBER-2022-1614-3766793

US3862141
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 10:07:51
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
User entered '11 Oct 2020 12:00'	System	06 Oct 2020 17:40:54

FDA-CBER-2022-1614-3766794

US3862141
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 10:07:51
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
User entered '12 Oct 2020 11:59'	System	06 Oct 2020 17:40:54

FDA-CBER-2022-1614-3766795

US3862141
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 10:07:51
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
Data entry locked.	System	06 Oct 2020 17:40:54
User entered 'Day 7'	System	06 Oct 2020 17:40:54

FDA-CBER-2022-1614-3766796

US3862141
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 10:07:51
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-12T12:24:13', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'c028ed15-e9ef-4ed4-85a0-ce124bb1c1dc'	System	12 Oct 2020 17:24:40
User entered 'None (1)'	System	12 Oct 2020 17:24:40

FDA-CBER-2022-1614-3766797

US3862141
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 10:07:51
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-12T12:24:16', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'c028ed15-e9ef-4ed4-85a0-ce124bb1c1dc'	System	12 Oct 2020 17:24:40
User entered 'No (N)'	System	12 Oct 2020 17:24:40

FDA-CBER-2022-1614-3766798

US3862141
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 10:07:51
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-12T12:24:20', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'c028ed15-e9ef-4ed4-85a0-ce124bb1c1dc'	System	12 Oct 2020 17:24:40
User entered 'No (N)'	System	12 Oct 2020 17:24:40

FDA-CBER-2022-1614-3766799

US3862141
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 10:07:51
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-12T12:24:23', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'c028ed15-e9ef-4ed4-85a0-ce124bb1c1dc'	System	12 Oct 2020 17:24:40
User entered 'None (1)'	System	12 Oct 2020 17:24:40

US3862141
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 10:07:51
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-12T12:24:36', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'c028ed15-e9ef-4ed4-85a0-ce124bb1c1dc'	System	12 Oct 2020 17:24:40
User entered '12 Oct 2020 12:24'	System	12 Oct 2020 17:24:40

FDA-CBER-2022-1614-3766801

US3862141
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 10:07:51
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
User entered '12 Oct 2020 12:00'	System	06 Oct 2020 17:40:54

FDA-CBER-2022-1614-3766802

US3862141
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 10:07:51
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
User entered '13 Oct 2020 11:59'	System	06 Oct 2020 17:40:54

FDA-CBER-2022-1614-3766803

US3862141
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 10:07:51
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
Data entry locked.	System	06 Oct 2020 17:40:54
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Oct 2020 17:40:54

US3862141
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 10:07:51
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-06T13:27:39', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '89e58fff-4e73-4ccc-9099-aa1df1a8ee4a'	System	06 Oct 2020 18:28:05
User entered 'None (0)'	System	06 Oct 2020 18:28:05

FDA-CBER-2022-1614-3766805

US3862141
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 10:07:51
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-06T13:27:36', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '89e58fff-4e73-4ccc-9099-aa1df1a8ee4a'	System	06 Oct 2020 18:28:05
User entered 'None (0)'	System	06 Oct 2020 18:28:05

FDA-CBER-2022-1614-3766806

US3862141
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 10:07:51
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-06T13:27:42', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '89e58fff-4e73-4ccc-9099-aa1df1a8ee4a'	System	06 Oct 2020 18:28:05
User entered 'None (0)'	System	06 Oct 2020 18:28:05

FDA-CBER-2022-1614-3766807

US3862141
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 10:07:51
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-06T13:27:45', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '89e58fff-4e73-4ccc-9099-aa1df1a8ee4a'	System	06 Oct 2020 18:28:05
User entered 'None (0)'	System	06 Oct 2020 18:28:05

FDA-CBER-2022-1614-3766808

US3862141
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 10:07:51
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-06T13:27:48', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '89e58fff-4e73-4ccc-9099-aa1df1a8ee4a'	System	06 Oct 2020 18:28:05
User entered 'None (0)'	System	06 Oct 2020 18:28:05

FDA-CBER-2022-1614-3766809

US3862141
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 10:07:51
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-06T13:27:51', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '89e58fff-4e73-4ccc-9099-aa1df1a8ee4a'	System	06 Oct 2020 18:28:05
User entered 'None (0)'	System	06 Oct 2020 18:28:05

FDA-CBER-2022-1614-3766810

US3862141
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 10:07:51
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)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-06T13:27:57', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '89e58fff-4e73-4ccc-9099-aa1df1a8ee4a'	System	06 Oct 2020 18:28:05
User entered 'No (N)'	System	06 Oct 2020 18:28:05

FDA-CBER-2022-1614-3766811

US3862141
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 10:07:51
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-06T13:28:01', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '89e58fff-4e73-4ccc-9099-aa1df1a8ee4a'	System	06 Oct 2020 18:28:05
User entered '06 Oct 2020 13:28'	System	06 Oct 2020 18:28:05

FDA-CBER-2022-1614-3766812

US3862141
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 10:07:51
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
User entered '06 Oct 2020 12:57'	System	06 Oct 2020 17:40:54

FDA-CBER-2022-1614-3766813

US3862141
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 10:07:51
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
User entered '06 Oct 2020 15:27'	System	06 Oct 2020 17:40:54

FDA-CBER-2022-1614-3766814

US3862141
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 10:07:51
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
Data entry locked.	System	06 Oct 2020 17:40:54
User entered 'Day 1, after vaccination (at home)'	System	06 Oct 2020 17:40:54

US3862141
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 10:07:51
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-06T18:48:35', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'bc66ad46-ac77-441e-8aac-fccdede2abb3'	System	06 Oct 2020 23:49:20
User entered 'None (0)'	System	06 Oct 2020 23:49:20

FDA-CBER-2022-1614-3766816

US3862141
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 10:07:51
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-06T18:48:41', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'bc66ad46-ac77-441e-8aac-fccdede2abb3'	System	06 Oct 2020 23:49:20
User entered 'None (0)'	System	06 Oct 2020 23:49:20

US3862141
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 10:07:51
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-06T18:48:44', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'bc66ad46-ac77-441e-8aac-fccdede2abb3'	System	06 Oct 2020 23:49:20
User entered 'None (0)'	System	06 Oct 2020 23:49:20

FDA-CBER-2022-1614-3766818

US3862141
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 10:07:51
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-06T18:48:48', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'bc66ad46-ac77-441e-8aac-fccdede2abb3'	System	06 Oct 2020 23:49:20
User entered 'None (0)'	System	06 Oct 2020 23:49:20

FDA-CBER-2022-1614-3766819

US3862141
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 10:07:51
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-06T18:48:51', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'bc66ad46-ac77-441e-8aac-fccdede2abb3'	System	06 Oct 2020 23:49:20
User entered 'None (0)'	System	06 Oct 2020 23:49:20

FDA-CBER-2022-1614-3766820

US3862141
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 10:07:51
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-06T18:48:54', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'bc66ad46-ac77-441e-8aac-fccdede2abb3'	System	06 Oct 2020 23:49:20
User entered 'None (0)'	System	06 Oct 2020 23:49:20

FDA-CBER-2022-1614-3766821

US3862141
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 10:07:51
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)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-06T18:49:00', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'bc66ad46-ac77-441e-8aac-fccdede2abb3'	System	06 Oct 2020 23:49:20
User entered 'No (N)'	System	06 Oct 2020 23:49:20

FDA-CBER-2022-1614-3766822

US3862141
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 10:07:51
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-06T18:49:18', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'bc66ad46-ac77-441e-8aac-fccdede2abb3'	System	06 Oct 2020 23:49:20
User entered '06 Oct 2020 18:49'	System	06 Oct 2020 23:49:20

FDA-CBER-2022-1614-3766823

US3862141
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 10:07:51
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
User entered '06 Oct 2020 16:22'	System	06 Oct 2020 17:40:54

FDA-CBER-2022-1614-3766824

US3862141
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 10:07:51
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
User entered '07 Oct 2020 11:59'	System	06 Oct 2020 17:40:54

FDA-CBER-2022-1614-3766825

US3862141
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 10:07:51
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
Data entry locked.	System	06 Oct 2020 17:40:54
User entered 'Day 2'	System	06 Oct 2020 17:40:54

FDA-CBER-2022-1614-3766826

US3862141
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 10:07:51
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-07T12:23:12', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'a4d186aa-97b2-4e75-a220-85ed1a966888'	System	07 Oct 2020 17:23:40
User entered 'None (0)'	System	07 Oct 2020 17:23:40

FDA-CBER-2022-1614-3766827

US3862141
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 10:07:51
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-07T12:23:18', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'a4d186aa-97b2-4e75-a220-85ed1a966888'	System	07 Oct 2020 17:23:40
User entered 'None (0)'	System	07 Oct 2020 17:23:40

FDA-CBER-2022-1614-3766828

US3862141
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 10:07:51
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-07T12:23:21', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'a4d186aa-97b2-4e75-a220-85ed1a966888'	System	07 Oct 2020 17:23:40
User entered 'None (0)'	System	07 Oct 2020 17:23:40

FDA-CBER-2022-1614-3766829

US3862141
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 10:07:51
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-07T12:23:24', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'a4d186aa-97b2-4e75-a220-85ed1a966888'	System	07 Oct 2020 17:23:40
User entered 'None (0)'	System	07 Oct 2020 17:23:40

FDA-CBER-2022-1614-3766830

US3862141
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 10:07:51
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-07T12:23:26', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'a4d186aa-97b2-4e75-a220-85ed1a966888'	System	07 Oct 2020 17:23:40
User entered 'None (0)'	System	07 Oct 2020 17:23:40

FDA-CBER-2022-1614-3766831

US3862141
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 10:07:51
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-07T12:23:30', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'a4d186aa-97b2-4e75-a220-85ed1a966888'	System	07 Oct 2020 17:23:40
User entered 'None (0)'	System	07 Oct 2020 17:23:40

FDA-CBER-2022-1614-3766832

US3862141
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 10:07:51
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)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-07T12:23:33', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'a4d186aa-97b2-4e75-a220-85ed1a966888'	System	07 Oct 2020 17:23:40
User entered 'No (N)'	System	07 Oct 2020 17:23:40

FDA-CBER-2022-1614-3766833

US3862141
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 10:07:51
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-07T12:23:38', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'a4d186aa-97b2-4e75-a220-85ed1a966888'	System	07 Oct 2020 17:23:40
User entered '07 Oct 2020 12:23'	System	07 Oct 2020 17:23:40

FDA-CBER-2022-1614-3766834

US3862141
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 10:07:51
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
User entered '07 Oct 2020 12:00'	System	06 Oct 2020 17:40:54

FDA-CBER-2022-1614-3766835

US3862141
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 10:07:51
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
User entered '08 Oct 2020 11:59'	System	06 Oct 2020 17:40:54

FDA-CBER-2022-1614-3766836

US3862141
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 10:07:51
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
Data entry locked.	System	06 Oct 2020 17:40:54
User entered 'Day 3'	System	06 Oct 2020 17:40:54

FDA-CBER-2022-1614-3766837

US3862141
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 10:07:51
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-08T12:06:19', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '82bb72d9-5d3f-4d18-ac01-c91f5e2a2288'	System	08 Oct 2020 17:07:00
User entered 'None (0)'	System	08 Oct 2020 17:07:00

FDA-CBER-2022-1614-3766838

US3862141
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 10:07:51
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-08T12:06:31', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '82bb72d9-5d3f-4d18-ac01-c91f5e2a2288'	System	08 Oct 2020 17:07:00
User entered 'None (0)'	System	08 Oct 2020 17:07:00

FDA-CBER-2022-1614-3766839

US3862141
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 10:07:51
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-08T12:06:34', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '82bb72d9-5d3f-4d18-ac01-c91f5e2a2288'	System	08 Oct 2020 17:07:00
User entered 'None (0)'	System	08 Oct 2020 17:07:00

FDA-CBER-2022-1614-3766840

US3862141
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 10:07:51
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-08T12:06:38', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '82bb72d9-5d3f-4d18-ac01-c91f5e2a2288'	System	08 Oct 2020 17:07:00
User entered 'None (0)'	System	08 Oct 2020 17:07:00

FDA-CBER-2022-1614-3766841

US3862141
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 10:07:51
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-08T12:06:41', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '82bb72d9-5d3f-4d18-ac01-c91f5e2a2288'	System	08 Oct 2020 17:07:00
User entered 'None (0)'	System	08 Oct 2020 17:07:00

FDA-CBER-2022-1614-3766842

US3862141
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 10:07:51
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-08T12:06:43', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '82bb72d9-5d3f-4d18-ac01-c91f5e2a2288'	System	08 Oct 2020 17:07:00
User entered 'None (0)'	System	08 Oct 2020 17:07:00

FDA-CBER-2022-1614-3766843

US3862141
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 10:07:51
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)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-08T12:06:48', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '82bb72d9-5d3f-4d18-ac01-c91f5e2a2288'	System	08 Oct 2020 17:07:00
User entered 'No (N)'	System	08 Oct 2020 17:07:00

FDA-CBER-2022-1614-3766844

US3862141
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 10:07:51
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-08T12:06:53', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '82bb72d9-5d3f-4d18-ac01-c91f5e2a2288'	System	08 Oct 2020 17:07:00
User entered '08 Oct 2020 12:06'	System	08 Oct 2020 17:07:00

FDA-CBER-2022-1614-3766845

US3862141
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 10:07:51
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
User entered '08 Oct 2020 12:00'	System	06 Oct 2020 17:40:54

FDA-CBER-2022-1614-3766846

US3862141
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 10:07:51
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
User entered '09 Oct 2020 11:59'	System	06 Oct 2020 17:40:54

FDA-CBER-2022-1614-3766847

US3862141
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 10:07:51
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
Data entry locked.	System	06 Oct 2020 17:40:54
User entered 'Day 4'	System	06 Oct 2020 17:40:54

FDA-CBER-2022-1614-3766848

US3862141
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 10:07:51
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-09T13:50:55', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '2aeee1c2-f8d1-4311-bf09-aff7569e5d83'	System	09 Oct 2020 18:51:24
User entered 'None (0)'	System	09 Oct 2020 18:51:24

US3862141
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 10:07:51
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-09T13:51:00', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '2aeee1c2-f8d1-4311-bf09-aff7569e5d83'	System	09 Oct 2020 18:51:24
User entered 'None (0)'	System	09 Oct 2020 18:51:24

FDA-CBER-2022-1614-3766850

US3862141
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 10:07:51
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-09T13:51:04', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '2aeee1c2-f8d1-4311-bf09-aff7569e5d83'	System	09 Oct 2020 18:51:24
User entered 'None (0)'	System	09 Oct 2020 18:51:24

FDA-CBER-2022-1614-3766851

US3862141
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 10:07:51
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-09T13:51:07', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '2aeee1c2-f8d1-4311-bf09-aff7569e5d83'	System	09 Oct 2020 18:51:24
User entered 'None (0)'	System	09 Oct 2020 18:51:24

FDA-CBER-2022-1614-3766852

US3862141
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 10:07:51
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-09T13:51:09', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '2aeee1c2-f8d1-4311-bf09-aff7569e5d83'	System	09 Oct 2020 18:51:24
User entered 'None (0)'	System	09 Oct 2020 18:51:24

FDA-CBER-2022-1614-3766853

US3862141
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 10:07:51
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-09T13:51:12', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '2aeee1c2-f8d1-4311-bf09-aff7569e5d83'	System	09 Oct 2020 18:51:24
User entered 'None (0)'	System	09 Oct 2020 18:51:24

US3862141
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 10:07:51
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)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-09T13:51:15', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '2aeee1c2-f8d1-4311-bf09-aff7569e5d83'	System	09 Oct 2020 18:51:24
User entered 'No (N)'	System	09 Oct 2020 18:51:24

FDA-CBER-2022-1614-3766855

US3862141
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 10:07:51
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-09T13:51:19', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '2aeee1c2-f8d1-4311-bf09-aff7569e5d83'	System	09 Oct 2020 18:51:24
User entered '09 Oct 2020 13:51'	System	09 Oct 2020 18:51:24

FDA-CBER-2022-1614-3766856

US3862141
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 10:07:51
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
User entered '09 Oct 2020 12:00'	System	06 Oct 2020 17:40:54

US3862141
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 10:07:51
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
User entered '10 Oct 2020 11:59'	System	06 Oct 2020 17:40:54

FDA-CBER-2022-1614-3766858

US3862141
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 10:07:51
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
Data entry locked.	System	06 Oct 2020 17:40:54
User entered 'Day 5'	System	06 Oct 2020 17:40:54

FDA-CBER-2022-1614-3766859

US3862141
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 10:07:51
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-10T12:42:11', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'e6f878bf-d5a6-4275-acd2-0c44044ab4de'	System	10 Oct 2020 17:42:56
User entered 'None (0)'	System	10 Oct 2020 17:42:56

FDA-CBER-2022-1614-3766860

US3862141
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 10:07:51
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-10T12:42:14', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'e6f878bf-d5a6-4275-acd2-0c44044ab4de'	System	10 Oct 2020 17:42:56
User entered 'None (0)'	System	10 Oct 2020 17:42:56

FDA-CBER-2022-1614-3766861

US3862141
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 10:07:51
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-10T12:42:20', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'e6f878bf-d5a6-4275-acd2-0c44044ab4de'	System	10 Oct 2020 17:42:56
User entered 'None (0)'	System	10 Oct 2020 17:42:56

FDA-CBER-2022-1614-3766862

US3862141
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 10:07:51
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-10T12:42:27', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'e6f878bf-d5a6-4275-acd2-0c44044ab4de'	System	10 Oct 2020 17:42:56
User entered 'None (0)'	System	10 Oct 2020 17:42:56

FDA-CBER-2022-1614-3766863

US3862141
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 10:07:51
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-10T12:42:29', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'e6f878bf-d5a6-4275-acd2-0c44044ab4de'	System	10 Oct 2020 17:42:56
User entered 'None (0)'	System	10 Oct 2020 17:42:56

FDA-CBER-2022-1614-3766864

US3862141
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 10:07:51
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-10T12:42:32', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'e6f878bf-d5a6-4275-acd2-0c44044ab4de'	System	10 Oct 2020 17:42:56
User entered 'None (0)'	System	10 Oct 2020 17:42:56

FDA-CBER-2022-1614-3766865

US3862141
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 10:07:51
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)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-10T12:42:37', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'e6f878bf-d5a6-4275-acd2-0c44044ab4de'	System	10 Oct 2020 17:42:56
User entered 'No (N)'	System	10 Oct 2020 17:42:56

FDA-CBER-2022-1614-3766866

US3862141
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 10:07:51
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-10T12:42:43', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'e6f878bf-d5a6-4275-acd2-0c44044ab4de'	System	10 Oct 2020 17:42:56
User entered '10 Oct 2020 12:42'	System	10 Oct 2020 17:42:56

FDA-CBER-2022-1614-3766867

US3862141
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 10:07:51
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
User entered '10 Oct 2020 12:00'	System	06 Oct 2020 17:40:54

FDA-CBER-2022-1614-3766868

US3862141
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 10:07:51
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
User entered '11 Oct 2020 11:59'	System	06 Oct 2020 17:40:54

FDA-CBER-2022-1614-3766869

US3862141
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 10:07:51
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
Data entry locked.	System	06 Oct 2020 17:40:54
User entered 'Day 6'	System	06 Oct 2020 17:40:54

US3862141
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 10:07:51
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-11T13:36:36', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '94cbf183-e791-4fb0-9882-43aa17ebcae6'	System	11 Oct 2020 18:37:02
User entered 'None (0)'	System	11 Oct 2020 18:37:02

FDA-CBER-2022-1614-3766871

US3862141
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 10:07:51
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-11T13:36:39', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '94cbf183-e791-4fb0-9882-43aa17ebcae6'	System	11 Oct 2020 18:37:02
User entered 'None (0)'	System	11 Oct 2020 18:37:02

FDA-CBER-2022-1614-3766872

US3862141
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 10:07:51
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-11T13:36:42', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '94cbf183-e791-4fb0-9882-43aa17ebcae6'	System	11 Oct 2020 18:37:02
User entered 'None (0)'	System	11 Oct 2020 18:37:02

US3862141
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 10:07:51
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-11T13:36:44', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '94cbf183-e791-4fb0-9882-43aa17ebcae6'	System	11 Oct 2020 18:37:02
User entered 'None (0)'	System	11 Oct 2020 18:37:02

FDA-CBER-2022-1614-3766874

US3862141
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 10:07:51
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-11T13:36:47', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '94cbf183-e791-4fb0-9882-43aa17ebcae6'	System	11 Oct 2020 18:37:02
User entered 'None (0)'	System	11 Oct 2020 18:37:02

FDA-CBER-2022-1614-3766875

US3862141
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 10:07:51
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-11T13:36:49', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '94cbf183-e791-4fb0-9882-43aa17ebcae6'	System	11 Oct 2020 18:37:02
User entered 'None (0)'	System	11 Oct 2020 18:37:02

FDA-CBER-2022-1614-3766876

US3862141
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 10:07:51
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)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-11T13:36:52', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '94cbf183-e791-4fb0-9882-43aa17ebcae6'	System	11 Oct 2020 18:37:02
User entered 'Yes (Y)'	System	11 Oct 2020 18:37:02

FDA-CBER-2022-1614-3766877

US3862141
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 10:07:51
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-11T13:36:56', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '94cbf183-e791-4fb0-9882-43aa17ebcae6'	System	11 Oct 2020 18:37:02
User entered '11 Oct 2020 13:36'	System	11 Oct 2020 18:37:02

FDA-CBER-2022-1614-3766878

US3862141
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 10:07:51
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
User entered '11 Oct 2020 12:00'	System	06 Oct 2020 17:40:54

FDA-CBER-2022-1614-3766879

US3862141
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 10:07:51
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
User entered '12 Oct 2020 11:59'	System	06 Oct 2020 17:40:54

FDA-CBER-2022-1614-3766880

US3862141
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 10:07:51
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
Data entry locked.	System	06 Oct 2020 17:40:54
User entered 'Day 7'	System	06 Oct 2020 17:40:54

US3862141
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 10:07:51
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-12T12:24:42', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '7a155cfb-1d49-4ab5-86c8-a4fd8524fdba'	System	12 Oct 2020 17:25:20
User entered 'None (0)'	System	12 Oct 2020 17:25:20

FDA-CBER-2022-1614-3766882

US3862141
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 10:07:51
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-12T12:24:45', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '7a155cfb-1d49-4ab5-86c8-a4fd8524fdba'	System	12 Oct 2020 17:25:20
User entered 'None (0)'	System	12 Oct 2020 17:25:20

FDA-CBER-2022-1614-3766883

US3862141
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 10:07:51
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-12T12:24:47', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '7a155cfb-1d49-4ab5-86c8-a4fd8524fdba'	System	12 Oct 2020 17:25:20
User entered 'None (0)'	System	12 Oct 2020 17:25:20

FDA-CBER-2022-1614-3766884

US3862141
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 10:07:51
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-12T12:24:50', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '7a155cfb-1d49-4ab5-86c8-a4fd8524fdba'	System	12 Oct 2020 17:25:20
User entered 'None (0)'	System	12 Oct 2020 17:25:20

FDA-CBER-2022-1614-3766885

US3862141
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 10:07:51
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-12T12:24:52', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '7a155cfb-1d49-4ab5-86c8-a4fd8524fdba'	System	12 Oct 2020 17:25:20
User entered 'None (0)'	System	12 Oct 2020 17:25:20

FDA-CBER-2022-1614-3766886

US3862141
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 10:07:51
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-12T12:24:55', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '7a155cfb-1d49-4ab5-86c8-a4fd8524fdba'	System	12 Oct 2020 17:25:20
User entered 'None (0)'	System	12 Oct 2020 17:25:20

FDA-CBER-2022-1614-3766887

US3862141
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 10:07:51
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)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-12T12:24:58', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '7a155cfb-1d49-4ab5-86c8-a4fd8524fdba'	System	12 Oct 2020 17:25:20
User entered 'No (N)'	System	12 Oct 2020 17:25:20

FDA-CBER-2022-1614-3766888

US3862141
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 10:07:51
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-10-12T12:25:03', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '7a155cfb-1d49-4ab5-86c8-a4fd8524fdba'	System	12 Oct 2020 17:25:20
User entered '12 Oct 2020 12:25'	System	12 Oct 2020 17:25:20

FDA-CBER-2022-1614-3766889

US3862141
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 10:07:51
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
User entered '12 Oct 2020 12:00'	System	06 Oct 2020 17:40:54

FDA-CBER-2022-1614-3766890

US3862141
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 10:07:51
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
User entered '13 Oct 2020 11:59'	System	06 Oct 2020 17:40:54

FDA-CBER-2022-1614-3766891

US3862141
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 10 Jun 2021 10:07:51
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered 'Yes (Y)'	Shetel Anassi (b) (4) (b) (4)	13 Oct 2020 22:01:37

US3862141
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 10 Jun 2021 10:07:51
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered '13 Oct 2020'	Shetel Anassi (b) (4) (b) (4)	13 Oct 2020 22:01:37

US3862141
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 10 Jun 2021 10:07:51
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered 'Contact Made (CONTACT MADE)'	Shetel Anassi (b) (4) (b) (4)	13 Oct 2020 22:01:37

US3862141
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 10 Jun 2021 10:07:51
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered empty.	Shetel Anassi (b) (4) (b) (4)	13 Oct 2020 22:01:37

FDA-CBER-2022-1614-3766895

US3862141
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 10 Jun 2021 10:07:51
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered 'Yes (Y)'	Shetel Anassi (b) (4) (b) (4)	13 Oct 2020 22:01:43

US3862141
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 10 Jun 2021 10:07:51
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User entered '1'	System	13 Oct 2020 22:01:43

FDA-CBER-2022-1614-3766897

US3862141
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 10 Jun 2021 10:07:51
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered 'Yes (Y)'	Shetel Anassi (b) (4) (b) (4)	20 Oct 2020 20:50:28

FDA-CBER-2022-1614-3766898

US3862141
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 10 Jun 2021 10:07:51
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered '20 Oct 2020'	Shetel Anassi (b) (4) (b) (4)	20 Oct 2020 20:50:28

US3862141
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 10 Jun 2021 10:07:51
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered 'Contact Made (CONTACT MADE)'	Shetel Anassi (b) (4) (b) (4)	20 Oct 2020 20:50:28

US3862141
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 10 Jun 2021 10:07:51
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered empty.	Shetel Anassi (b) (4) (b) (4)	20 Oct 2020 20:50:28

FDA-CBER-2022-1614-3766901

US3862141
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 10 Jun 2021 10:07:51
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered 'Yes (Y)'	Shetel Anassi (b) (4) (b) (4)	20 Oct 2020 20:50:35

US3862141
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 10 Jun 2021 10:07:51
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User entered '1'	System	20 Oct 2020 20:50:35

US3862141
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 10 Jun 2021 10:07:51
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:49:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 21:21:31

US3862141
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 10 Jun 2021 10:07:51
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:49:55
User entered '27 Oct 2020'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 21:21:31

US3862141
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 10 Jun 2021 10:07:51
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:49:55
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 21:21:31

US3862141
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 10 Jun 2021 10:07:51
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:49:55
User entered empty.	(b) (4), (b) (6)	27 Oct 2020 21:21:31

FDA-CBER-2022-1614-3766907

US3862141
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 10 Jun 2021 10:07:51
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered 'Yes (Y)'	Trent Davis (b) (4) (b) (4)	03 Nov 2020 20:45:11

US3862141
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 10 Jun 2021 10:07:51
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User entered '1'	System	03 Nov 2020 20:45:11

US3862141
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 10 Jun 2021 10:07:51
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:25
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered 'Yes (Y)'	Trent Davis (b) (4) (b) (4)	03 Nov 2020 20:51:40

US3862141
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 10 Jun 2021 10:07:51
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:25
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered '3 Nov 2020'	Trent Davis (b) (4) (b) (4)	03 Nov 2020 20:51:40

FDA-CBER-2022-1614-3766911

US3862141
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 10 Jun 2021 10:07:51
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:25
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered 'Clinic (Clinic)'	Trent Davis (b) (4) (b) (4)	03 Nov 2020 20:51:40

US3862141
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 10 Jun 2021 10:07:51
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:25
User entered 'VISIT3'	System	03 Nov 2020 20:51:40

FDA-CBER-2022-1614-3766913

US3862141
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 10:07:51
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:25
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered 'Yes (Y)'	Trent Davis (b) (4) (b) (4)	03 Nov 2020 20:52:51

FDA-CBER-2022-1614-3766914

US3862141
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 10:07:51
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:25
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered '3 Nov 2020'	Trent Davis (b) (4) (b) (4)	03 Nov 2020 20:52:51

FDA-CBER-2022-1614-3766915

US3862141
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 10:07:51
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:25
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered '11:06'	Trent Davis (b) (4) (b) (4)	03 Nov 2020 20:52:51

US3862141
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 10:07:51
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:25
User entered '3 Nov 2020 11:06'	System	03 Nov 2020 20:52:51

FDA-CBER-2022-1614-3766917

US3862141
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 10:07:51
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:25
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered '098.0' F	Trent Davis (b) (4) (b) (4)	03 Nov 2020 20:52:51

FDA-CBER-2022-1614-3766918

US3862141
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 10:07:51
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:25
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered 'Other (Other)'	Trent Davis (b) (4) (b) (4)	03 Nov 2020 20:52:51

FDA-CBER-2022-1614-3766919

US3862141
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 10:07:51
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:25
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered 'temporal'	Trent Davis (b) (4) (b) (4)	03 Nov 2020 20:52:51

US3862141
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 10:07:51
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:25
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered '060'	Trent Davis (b) (4) (b) (4)	03 Nov 2020 20:52:51

FDA-CBER-2022-1614-3766921

US3862141
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 10:07:51
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:25
User entered 'bpm'	System	03 Nov 2020 20:52:51

FDA-CBER-2022-1614-3766922

US3862141
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 10:07:51
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:25
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User closed query 'Respiratory rate reported is out of range < 8 or > 32 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	04 Nov 2020 18:51:31
Query 'Respiratory rate reported is out of range < 8 or > 32 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	04 Nov 2020 18:51:31
User entered '012' reason for change: Data Entry Error	Trent Davis (b) (4) (b) (4)	04 Nov 2020 18:51:31
User opened query 'Respiratory rate reported is out of range < 8 or > 32 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	03 Nov 2020 20:52:51
User entered '063'	Trent Davis (b) (4) (b) (4)	03 Nov 2020 20:52:51

US3862141
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 10:07:51
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:25
User entered 'breaths/min'	System	03 Nov 2020 20:52:51

FDA-CBER-2022-1614-3766924

US3862141
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 10:07:51
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:25
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered '115'	Trent Davis (b) (4) (b) (4)	03 Nov 2020 20:52:51

FDA-CBER-2022-1614-3766925

US3862141
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 10:07:51
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:25
User entered 'mmHg'	System	03 Nov 2020 20:52:51

FDA-CBER-2022-1614-3766926

US3862141
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 10:07:51
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:25
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered '060'	Trent Davis (b) (4) (b) (4)	03 Nov 2020 20:52:51

FDA-CBER-2022-1614-3766927

US3862141
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 10:07:51
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:25
User entered 'mmHg'	System	03 Nov 2020 20:52:51

FDA-CBER-2022-1614-3766928

US3862141
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 10:07:51
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:25

FDA-CBER-2022-1614-3766929

US3862141
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 10:07:51
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:25

FDA-CBER-2022-1614-3766930

US3862141
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Generated On: 10 Jun 2021 10:07:51
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:25
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered 'No (N)'	Trent Davis (b) (4) (b) (4)	03 Nov 2020 20:53:05

FDA-CBER-2022-1614-3766931

US3862141
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Generated On: 10 Jun 2021 10:07:51
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:25
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered empty.	Trent Davis (b) (4) (b) (4)	03 Nov 2020 20:53:05

FDA-CBER-2022-1614-3766932

US3862141
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 10:07:51
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:25
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered 'Yes (Y)'	Trent Davis (b) (4) (b) (4)	03 Nov 2020 20:53:16

FDA-CBER-2022-1614-3766933

US3862141
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 10:07:51
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:25
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered '3 Nov 2020'	Trent Davis (b) (4) (b) (4)	03 Nov 2020 20:53:16

FDA-CBER-2022-1614-3766934

US3862141
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 10:07:51
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:25
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered '11:45'	Trent Davis (b) (4) (b) (4)	03 Nov 2020 20:53:16

FDA-CBER-2022-1614-3766935

US3862141
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 10:07:51
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:25
User entered '3 Nov 2020 11:45'	System	03 Nov 2020 20:53:16

FDA-CBER-2022-1614-3766936

US3862141
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 10 Jun 2021 10:07:51
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:25
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:49:55
User entered 'Yes (Y)'	Chanei Henry (b) (4) (b) (4)	01 Dec 2020 18:23:13

US3862141
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 10 Jun 2021 10:07:51
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:25
User entered '1'	System	01 Dec 2020 18:23:13

FDA-CBER-2022-1614-3766938

US3862141
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:07:51
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
Data entry locked.	System	08 Sep 2020 17:55:18
User entered 'Day 64'	System	08 Sep 2020 17:55:18

FDA-CBER-2022-1614-3766939

US3862141

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:07:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-11-09T14:35:17', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '3f3f4c95-1cf6-4e72-af13-7246fab1a099'	System	09 Nov 2020 20:35:31
User entered 'No (N)'	System	09 Nov 2020 20:35:31

US3862141

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:07:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-11-09T14:35:23', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '3f3f4c95-1cf6-4e72-af13-7246fab1a099'	System	09 Nov 2020 20:35:31
User entered 'No (N)'	System	09 Nov 2020 20:35:31

US3862141
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:07:51
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-11-09T14:35:30', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '3f3f4c95-1cf6-4e72-af13-7246fab1a099'	System	09 Nov 2020 20:35:31
User entered '09 Nov 2020 14:35:30'	System	09 Nov 2020 20:35:31

FDA-CBER-2022-1614-3766942

US3862141
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:07:51
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
Data entry locked.	System	08 Sep 2020 17:55:18
User entered '08 Nov 2020 00:01'	System	08 Sep 2020 17:55:18

US3862141
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:07:51
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
Data entry locked.	System	08 Sep 2020 17:55:18
User entered '12 Nov 2020 23:59'	System	08 Sep 2020 17:55:18

FDA-CBER-2022-1614-3766944

US3862141
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:07:51
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
Data entry locked.	System	08 Sep 2020 17:55:18
User entered 'Day 71'	System	08 Sep 2020 17:55:18

FDA-CBER-2022-1614-3766945

US3862141

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:07:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-11-16T10:41:17', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '58f1c50b-f992-469d-8e7a-41c14a460ffa'	System	16 Nov 2020 16:41:37
User entered 'No (N)'	System	16 Nov 2020 16:41:37

US3862141

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:07:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-11-16T10:41:27', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '58f1c50b-f992-469d-8e7a-41c14a460ffa'	System	16 Nov 2020 16:41:37
User entered 'No (N)'	System	16 Nov 2020 16:41:37

US3862141
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:07:51
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-11-16T10:41:34', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '58f1c50b-f992-469d-8e7a-41c14a460ffa'	System	16 Nov 2020 16:41:37
User entered '16 Nov 2020 10:41:34'	System	16 Nov 2020 16:41:37

US3862141
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:07:51
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
Data entry locked.	System	08 Sep 2020 17:55:18
User entered '15 Nov 2020 00:01'	System	08 Sep 2020 17:55:18

US3862141
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:07:51
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:42:20
Data entry locked.	System	08 Sep 2020 17:55:18
User entered '19 Nov 2020 23:59'	System	08 Sep 2020 17:55:18

FDA-CBER-2022-1614-3766950

US3862141
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:07:51
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:38
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 06:10:38

US3862141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:07:51

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-11-22T16:05:16', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '002623f0-faa0-4905-a3b4-c73bb617a3cd'	System	22 Nov 2020 22:05:31
User entered 'No (N)'	System	22 Nov 2020 22:05:31

US3862141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:07:51

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-11-22T16:05:23', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '002623f0-faa0-4905-a3b4-c73bb617a3cd'	System	22 Nov 2020 22:05:31
User entered 'No (N)'	System	22 Nov 2020 22:05:31

US3862141
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:07:51
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-11-22T16:05:29', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '002623f0-faa0-4905-a3b4-c73bb617a3cd'	System	22 Nov 2020 22:05:31
User entered '22 Nov 2020 16:05:29'	System	22 Nov 2020 22:05:31

US3862141
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:07:51
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:38
Amendment Manager: User entered '19 Nov 2020 00:01'	System	20 Nov 2020 06:10:38

US3862141
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:07:51
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:38
Amendment Manager: User entered '23 Nov 2020 23:59'	System	20 Nov 2020 06:10:38

US3862141
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:07:51
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:38
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 06:10:38

US3862141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:07:51

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-11-28T12:01:51', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '1c604716-b3e2-4e6d-829e-0fa9b6e5d68c'	System	28 Nov 2020 18:02:09
User entered 'No (N)'	System	28 Nov 2020 18:02:09

US3862141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:07:51

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-11-28T12:01:57', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '1c604716-b3e2-4e6d-829e-0fa9b6e5d68c'	System	28 Nov 2020 18:02:09
User entered 'No (N)'	System	28 Nov 2020 18:02:09

US3862141
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:07:51
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-11-28T12:02:04', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '1c604716-b3e2-4e6d-829e-0fa9b6e5d68c'	System	28 Nov 2020 18:02:09
User entered '28 Nov 2020 12:02:04'	System	28 Nov 2020 18:02:09

US3862141
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:07:51
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:38
Amendment Manager: User entered '26 Nov 2020 00:01'	System	20 Nov 2020 06:10:38

US3862141
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:07:51
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:38
Amendment Manager: User entered '30 Nov 2020 23:59'	System	20 Nov 2020 06:10:38

US3862141
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:07:51
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:38
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 06:10:38

US3862141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:07:51

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-12-05T10:53:19', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '61fd30c5-b150-495c-9a05-0fdefbb600cf'	System	05 Dec 2020 16:53:35
User entered 'No (N)'	System	05 Dec 2020 16:53:35

US3862141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:07:51

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-12-05T10:53:26', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '61fd30c5-b150-495c-9a05-0fdefbb600cf'	System	05 Dec 2020 16:53:35
User entered 'No (N)'	System	05 Dec 2020 16:53:35

US3862141
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:07:51
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-12-05T10:53:32', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '61fd30c5-b150-495c-9a05-0fdefbb600cf'	System	05 Dec 2020 16:53:35
User entered '05 Dec 2020 10:53:32'	System	05 Dec 2020 16:53:35

US3862141
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:07:51
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:38
Amendment Manager: User entered '03 Dec 2020 00:01'	System	20 Nov 2020 06:10:38

US3862141
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:07:51
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:38
Amendment Manager: User entered '07 Dec 2020 23:59'	System	20 Nov 2020 06:10:38

US3862141
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:07:51
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:38
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 06:10:38

US3862141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:07:51

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-12-12T16:12:02', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '2c765684-9999-43ba-b780-ca5e4f707f8c'	System	12 Dec 2020 22:12:17
User entered 'No (N)'	System	12 Dec 2020 22:12:17

US3862141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:07:51

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-12-12T16:12:08', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '2c765684-9999-43ba-b780-ca5e4f707f8c'	System	12 Dec 2020 22:12:17
User entered 'No (N)'	System	12 Dec 2020 22:12:17

US3862141
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:07:51
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-12-12T16:12:13', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '2c765684-9999-43ba-b780-ca5e4f707f8c'	System	12 Dec 2020 22:12:17
User entered '12 Dec 2020 16:12:13'	System	12 Dec 2020 22:12:17

US3862141
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:07:51
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:38
Amendment Manager: User entered '10 Dec 2020 00:01'	System	20 Nov 2020 06:10:38

US3862141
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:07:51
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:38
Amendment Manager: User entered '14 Dec 2020 23:59'	System	20 Nov 2020 06:10:38

US3862141
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:07:51
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:38
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 06:10:38

US3862141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:07:51

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-12-17T12:10:10', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'e80d9c5c-9cd0-4dd8-9402-f0f6fac3e592'	System	17 Dec 2020 18:10:28
User entered 'No (N)'	System	17 Dec 2020 18:10:28

US3862141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:07:51

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-12-17T12:10:18', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'e80d9c5c-9cd0-4dd8-9402-f0f6fac3e592'	System	17 Dec 2020 18:10:28
User entered 'No (N)'	System	17 Dec 2020 18:10:28

US3862141
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:07:51
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-12-17T12:10:22', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'e80d9c5c-9cd0-4dd8-9402-f0f6fac3e592'	System	17 Dec 2020 18:10:28
User entered '17 Dec 2020 12:10:22'	System	17 Dec 2020 18:10:28

US3862141
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:07:51
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:38
Amendment Manager: User entered '17 Dec 2020 00:01'	System	20 Nov 2020 06:10:38

US3862141
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:07:51
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:38
Amendment Manager: User entered '21 Dec 2020 23:59'	System	20 Nov 2020 06:10:38

US3862141
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:07:51
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:38
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 06:10:38

US3862141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:07:51

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-12-25T13:17:27', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '3b828955-9b22-486d-b85c-d441f519f095'	System	25 Dec 2020 19:17:39
User entered 'No (N)'	System	25 Dec 2020 19:17:39

US3862141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:07:51

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-12-25T13:17:33', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '3b828955-9b22-486d-b85c-d441f519f095'	System	25 Dec 2020 19:17:39
User entered 'No (N)'	System	25 Dec 2020 19:17:39

US3862141
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:07:51
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2020-12-25T13:17:37', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '3b828955-9b22-486d-b85c-d441f519f095'	System	25 Dec 2020 19:17:39
User entered '25 Dec 2020 13:17:37'	System	25 Dec 2020 19:17:39

US3862141
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:07:51
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:38
Amendment Manager: User entered '24 Dec 2020 00:01'	System	20 Nov 2020 06:10:38

US3862141
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:07:51
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:38
Amendment Manager: User entered '28 Dec 2020 23:59'	System	20 Nov 2020 06:10:38

US3862141
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:07:51
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:38
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 06:10:38

US3862141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:07:51

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2021-01-01T09:01:46', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '72ae2aaa-4967-45f9-b105-8c13c140f3fb'	System	01 Jan 2021 15:02:05
User entered 'No (N)'	System	01 Jan 2021 15:02:05

US3862141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:07:51

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2021-01-01T09:01:55', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '72ae2aaa-4967-45f9-b105-8c13c140f3fb'	System	01 Jan 2021 15:02:05
User entered 'No (N)'	System	01 Jan 2021 15:02:05

US3862141
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:07:51
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2021-01-01T09:02:00', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '72ae2aaa-4967-45f9-b105-8c13c140f3fb'	System	01 Jan 2021 15:02:05
User entered '01 Jan 2021 09:02:00'	System	01 Jan 2021 15:02:05

US3862141
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:07:51
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:38
Amendment Manager: User entered '31 Dec 2020 00:01'	System	20 Nov 2020 06:10:38

US3862141
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:07:51
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:38
Amendment Manager: User entered '04 Jan 2021 23:59'	System	20 Nov 2020 06:10:38

US3862141
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:07:51
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:38
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 06:10:38

US3862141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:07:51

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2021-01-08T18:31:51', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '10b475ae-7309-4080-80bf-fbd3471aa08b'	System	09 Jan 2021 00:32:04
User entered 'No (N)'	System	09 Jan 2021 00:32:04

US3862141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:07:51

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2021-01-08T18:31:57', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '10b475ae-7309-4080-80bf-fbd3471aa08b'	System	09 Jan 2021 00:32:04
User entered 'No (N)'	System	09 Jan 2021 00:32:04

US3862141
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:07:51
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2021-01-08T18:32:01', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '10b475ae-7309-4080-80bf-fbd3471aa08b'	System	09 Jan 2021 00:32:04
User entered '08 Jan 2021 18:32:01'	System	09 Jan 2021 00:32:04

US3862141
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:07:51
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:38
Amendment Manager: User entered '07 Jan 2021 00:01'	System	20 Nov 2020 06:10:38

US3862141
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:07:51
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:38
Amendment Manager: User entered '11 Jan 2021 23:59'	System	20 Nov 2020 06:10:38

US3862141
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:07:51
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:38
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 06:10:38

US3862141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:07:51

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2021-01-15T20:10:35', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '756dedc9-b32d-4f46-abf0-a6d2f39e34f2'	System	16 Jan 2021 02:10:51
User entered 'No (N)'	System	16 Jan 2021 02:10:51

US3862141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:07:51

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2021-01-15T20:10:43', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '756dedc9-b32d-4f46-abf0-a6d2f39e34f2'	System	16 Jan 2021 02:10:51
User entered 'No (N)'	System	16 Jan 2021 02:10:51

US3862141
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:07:51
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2021-01-15T20:10:46', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '756dedc9-b32d-4f46-abf0-a6d2f39e34f2'	System	16 Jan 2021 02:10:51
User entered '15 Jan 2021 20:10:46'	System	16 Jan 2021 02:10:51

US3862141
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:07:51
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:38
Amendment Manager: User entered '14 Jan 2021 00:01'	System	20 Nov 2020 06:10:38

US3862141
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:07:51
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:38
Amendment Manager: User entered '18 Jan 2021 23:59'	System	20 Nov 2020 06:10:38

US3862141
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:07:51
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:38
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 06:10:38

US3862141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:07:51

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2021-01-23T12:23:34', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'e5a1729d-dd64-4525-8c03-e1932c4b2fce'	System	23 Jan 2021 18:23:49
User entered 'No (N)'	System	23 Jan 2021 18:23:49

US3862141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:07:51

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2021-01-23T12:23:43', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'e5a1729d-dd64-4525-8c03-e1932c4b2fce'	System	23 Jan 2021 18:23:49
User entered 'No (N)'	System	23 Jan 2021 18:23:49

US3862141
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:07:51
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2021-01-23T12:23:47', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'e5a1729d-dd64-4525-8c03-e1932c4b2fce'	System	23 Jan 2021 18:23:49
User entered '23 Jan 2021 12:23:47'	System	23 Jan 2021 18:23:49

US3862141
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:07:51
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:38
Amendment Manager: User entered '21 Jan 2021 00:01'	System	20 Nov 2020 06:10:38

US3862141
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:07:51
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:38
Amendment Manager: User entered '25 Jan 2021 23:59'	System	20 Nov 2020 06:10:38

US3862141
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:07:51
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:38
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 06:10:38

US3862141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:07:51

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2021-01-28T18:00:12', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '8d0820f5-0193-42d6-835e-b4d7e5be6532'	System	29 Jan 2021 00:00:27
User entered 'No (N)'	System	29 Jan 2021 00:00:27

US3862141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:07:51

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2021-01-28T18:00:18', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '8d0820f5-0193-42d6-835e-b4d7e5be6532'	System	29 Jan 2021 00:00:27
User entered 'No (N)'	System	29 Jan 2021 00:00:27

US3862141
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:07:51
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2021-01-28T18:00:22', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '8d0820f5-0193-42d6-835e-b4d7e5be6532'	System	29 Jan 2021 00:00:27
User entered '28 Jan 2021 18:00:22'	System	29 Jan 2021 00:00:27

US3862141
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:07:51
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:38
Amendment Manager: User entered '28 Jan 2021 00:01'	System	20 Nov 2020 06:10:38

US3862141
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:07:51
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:38
Amendment Manager: User entered '01 Feb 2021 23:59'	System	20 Nov 2020 06:10:38

US3862141
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:07:51
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:38
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 06:10:38

US3862141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:07:51

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2021-02-05T10:03:40', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '7a0b79b9-5f41-4796-8eb3-ee8e17124b53'	System	05 Feb 2021 16:03:51
User entered 'No (N)'	System	05 Feb 2021 16:03:51

US3862141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:07:51

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2021-02-05T10:03:45', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '7a0b79b9-5f41-4796-8eb3-ee8e17124b53'	System	05 Feb 2021 16:03:51
User entered 'No (N)'	System	05 Feb 2021 16:03:51

US3862141
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:07:51
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2021-02-05T10:03:48', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '7a0b79b9-5f41-4796-8eb3-ee8e17124b53'	System	05 Feb 2021 16:03:51
User entered '05 Feb 2021 10:03:48'	System	05 Feb 2021 16:03:51

US3862141
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:07:51
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:38
Amendment Manager: User entered '04 Feb 2021 00:01'	System	20 Nov 2020 06:10:38

US3862141
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:07:51
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:38
Amendment Manager: User entered '08 Feb 2021 23:59'	System	20 Nov 2020 06:10:38

US3862141
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:07:51
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:38
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 06:10:38

US3862141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:07:51

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2021-02-11T13:40:18', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '7d093406-f056-4478-9459-ea2ca0207c43'	System	11 Feb 2021 19:40:29
User entered 'No (N)'	System	11 Feb 2021 19:40:29

US3862141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:07:51

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2021-02-11T13:40:23', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '7d093406-f056-4478-9459-ea2ca0207c43'	System	11 Feb 2021 19:40:29
User entered 'No (N)'	System	11 Feb 2021 19:40:29

US3862141
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:07:51
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2021-02-11T13:40:27', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '7d093406-f056-4478-9459-ea2ca0207c43'	System	11 Feb 2021 19:40:29
User entered '11 Feb 2021 13:40:27'	System	11 Feb 2021 19:40:29

US3862141
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:07:51
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:38
Amendment Manager: User entered '11 Feb 2021 00:01'	System	20 Nov 2020 06:10:38

US3862141
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:07:51
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:38
Amendment Manager: User entered '15 Feb 2021 23:59'	System	20 Nov 2020 06:10:38

US3862141
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:07:51
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:38
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 06:10:38

US3862141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:07:51

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2021-02-19T11:13:44', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '35a9dfdf-de32-484b-8221-785a70a0db9c'	System	19 Feb 2021 17:18:53
User entered 'No (N)'	System	19 Feb 2021 17:18:53

US3862141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:07:51

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2021-02-19T11:13:51', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '35a9dfdf-de32-484b-8221-785a70a0db9c'	System	19 Feb 2021 17:18:53
User entered 'No (N)'	System	19 Feb 2021 17:18:53

US3862141
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:07:51
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2021-02-19T11:13:56', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: '35a9dfdf-de32-484b-8221-785a70a0db9c'	System	19 Feb 2021 17:18:53
User entered '19 Feb 2021 11:13:56'	System	19 Feb 2021 17:18:53

US3862141
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:07:51
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:38
Amendment Manager: User entered '18 Feb 2021 00:01'	System	20 Nov 2020 06:10:38

US3862141
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:07:51
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:38
Amendment Manager: User entered '22 Feb 2021 23:59'	System	20 Nov 2020 06:10:38

US3862141
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:07:51
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:38
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 06:10:38

US3862141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:07:51

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2021-02-26T09:42:55-06:00', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'ec534a3d-678a-4d01-9637-484e242de25e'	System	26 Feb 2021 15:43:35
User entered 'No (N)'	System	26 Feb 2021 15:43:35

US3862141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:07:51

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2021-02-26T09:43:27-06:00', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'ec534a3d-678a-4d01-9637-484e242de25e'	System	26 Feb 2021 15:43:35
User entered 'No (N)'	System	26 Feb 2021 15:43:35

US3862141
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:07:51
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2021-02-26T09:43:31-06:00', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'ec534a3d-678a-4d01-9637-484e242de25e'	System	26 Feb 2021 15:43:35
User entered '26 Feb 2021 15:43:31'	System	26 Feb 2021 15:43:35

US3862141
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:07:51
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:38
Amendment Manager: User entered '25 Feb 2021 00:01'	System	20 Nov 2020 06:10:38

US3862141
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:07:51
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:38
Amendment Manager: User entered '01 Mar 2021 23:59'	System	20 Nov 2020 06:10:38

US3862141
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:07:51
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:38
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 06:10:38

US3862141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:07:51

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2021-03-04T11:20:08-06:00', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'c8e57550-5a23-4082-96fa-77a484518384'	System	04 Mar 2021 17:22:41
User entered 'No (N)'	System	04 Mar 2021 17:22:41

US3862141

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:07:51

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2021-03-04T11:20:15-06:00', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'c8e57550-5a23-4082-96fa-77a484518384'	System	04 Mar 2021 17:22:41
User entered 'No (N)'	System	04 Mar 2021 17:22:41

US3862141
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:07:51
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2021-03-04T11:20:18-06:00', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'c8e57550-5a23-4082-96fa-77a484518384'	System	04 Mar 2021 17:22:41
User entered '04 Mar 2021 11:20:18'	System	04 Mar 2021 17:22:41

US3862141
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:07:51
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:38
Amendment Manager: User entered '04 Mar 2021 00:01'	System	20 Nov 2020 06:10:38

US3862141
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 10:07:51
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:10:38
Amendment Manager: User entered '08 Mar 2021 23:59'	System	20 Nov 2020 06:10:38

US3862141

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 10:07:51

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:25:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2021-03-03T16:49:35-06:00', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'e63b0cb3-c0d3-4843-8a25-3a99d661878e'	System	03 Mar 2021 22:49:44
User entered 'No (N)'	System	03 Mar 2021 22:49:44

US3862141
Folder: Cosmetic Injections and Dermal Fillers
Form: Cosmetic Injection_ Dermal Filler eDiary (1)
Generated On: 10 Jun 2021 10:07:51
Date & Time of Submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:25:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ABB8FE2E-9057-46F3-A267-FEB5A8039510)', Time: '2021-03-03T16:49:42-06:00', User OID: 'PatientReportedOutcome (US3862141)', ODM File OID: 'e63b0cb3-c0d3-4843-8a25-3a99d661878e'	System	03 Mar 2021 22:49:44
User entered '03 Mar 2021 16:49:42'	System	03 Mar 2021 22:49:44

US3862141
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 10 Jun 2021 10:07:51
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	05 Mar 2021 22:31:17
User entered 'Yes (Y)'	Chanei Henry (b) (4) (b) (4)	01 Dec 2020 18:23:22

US3862141
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 10 Jun 2021 10:07:51
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	05 Mar 2021 22:31:17
User entered '01 Dec 2020' reason for change: Data Entry Error	Carrie Kibler (b) (4) (b) (4)	03 Mar 2021 14:55:18
User entered '1 Dec 2020'	Chanei Henry (b) (4) (b) (4)	01 Dec 2020 18:23:22

US3862141
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 10 Jun 2021 10:07:51
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	05 Mar 2021 22:31:17
User entered 'Contact Made (CONTACT MADE)'	Chanei Henry (b) (4) (b) (4)	01 Dec 2020 18:23:22

US3862141
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 10 Jun 2021 10:07:51
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	05 Mar 2021 22:31:17
User entered empty.	Chanei Henry (b) (4) (b) (4)	01 Dec 2020 18:23:22

US3862141
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 10 Jun 2021 10:07:51
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	05 Mar 2021 22:31:17
User entered 'Yes (Y)'	Chanei Henry (b) (4) (b) (4)	01 Dec 2020 18:23:26

US3862141
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 10 Jun 2021 10:07:51
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:04
User entered '1'	System	01 Dec 2020 18:23:26

FDA-CBER-2022-1614-3767054

US3862141
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 10 Jun 2021 10:07:51
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:55:33
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:26:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:31:33

FDA-CBER-2022-1614-3767055

US3862141
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 10 Jun 2021 10:07:51
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:55:33
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:26:25
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:31:33

US3862141
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 10 Jun 2021 10:07:51
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:55:33
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:26:25
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:31:33

FDA-CBER-2022-1614-3767057

US3862141
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 10 Jun 2021 10:07:51
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:55:33
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:26:25
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:31:33

FDA-CBER-2022-1614-3767058

US3862141
Folder: Safety Call Day 119 (1)
Form: Continuing
Generated On: 10 Jun 2021 10:07:51
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:55:33
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:26:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:31:43

US3862141
Folder: Safety Call Day 119 (1)
Form: Continuing
Generated On: 10 Jun 2021 10:07:51
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:55:33
User entered '1'	System	08 Mar 2021 16:31:43

FDA-CBER-2022-1614-3767060

US3862141
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 10 Jun 2021 10:07:51
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:55:33
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:32:05

FDA-CBER-2022-1614-3767061

US3862141
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 10 Jun 2021 10:07:51
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:55:33
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:13
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:32:05

US3862141
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 10 Jun 2021 10:07:51
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:55:33
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:13
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:32:05

FDA-CBER-2022-1614-3767063

US3862141
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 10 Jun 2021 10:07:51
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:55:33
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:13
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:32:05

FDA-CBER-2022-1614-3767064

US3862141
Folder: Safety Call Day 149 (1)
Form: Continuing
Generated On: 10 Jun 2021 10:07:51
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:55:33
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:26:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:32:13

US3862141
Folder: Safety Call Day 149 (1)
Form: Continuing
Generated On: 10 Jun 2021 10:07:51
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:55:33
User entered '1'	System	08 Mar 2021 16:32:13

FDA-CBER-2022-1614-3767066

US3862141
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 10 Jun 2021 10:07:51
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:55:33
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:32:40

US3862141
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 10 Jun 2021 10:07:51
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:55:33
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:13
User entered '5 Mar 2021'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:32:40

FDA-CBER-2022-1614-3767068

US3862141
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 10 Jun 2021 10:07:51
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:55:33
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:13
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:32:40

FDA-CBER-2022-1614-3767069

US3862141
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 10 Jun 2021 10:07:51
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:55:33
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:13
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:32:40

FDA-CBER-2022-1614-3767070

US3862141
Folder: Safety Call Day 179 (1)
Form: Continuing
Generated On: 10 Jun 2021 10:07:51
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:55:33
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:32:51

FDA-CBER-2022-1614-3767071

US3862141
Folder: Safety Call Day 179 (1)
Form: Continuing
Generated On: 10 Jun 2021 10:07:51
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:55:33
User entered '1'	System	08 Mar 2021 16:32:51

FDA-CBER-2022-1614-3767072

US3862141
Folder: Adverse Events
Form: Adverse Events Summary
Generated On: 10 Jun 2021 10:07:51
Did the participant experience any adverse events?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:35:03
User closed query 'Per CDM: Subject can no longer participate in study due to death from Cardiopulmonary Arrest as entered on the AE log. Please ensure End of Study/ Study discontinuation form is completed as required and reason for discontinuation is specified. ' (Site from DM).		22 Apr 2021 13:57:19
Query 'Per CDM: Subject can no longer participate in study due to death from Cardiopulmonary Arrest as entered on the AE log. Please ensure End of Study/ Study discontinuation form is completed as required and reason for discontinuation is specified. ' answered with 'End of Study EDC and source documentation completed on 20APR2021. ' (Site from DM).	Sandra Francisco (b) (4) (b) (4)	20 Apr 2021 18:39:27
User opened query 'Per CDM: Subject can no longer participate in study due to death from Cardiopulmonary Arrest as entered on the AE log. Please ensure End of Study/ Study discontinuation form is completed as required and reason for discontinuation is specified. ' (Site from DM).	(b) (4), (b) (6)	18 Apr 2021 19:29:15
Query 'Per CDM: Subject can no longer participate in study due to death from COVID 19 as entered on the AE log. Please ensure End of Study/ Study discontinuation form is completed as required and reason for discontinuation is specified. ' canceled (Site from DM).	(b) (4), (b) (6)	18 Apr 2021 19:27:53
User opened query 'Per CDM: Subject can no longer participate in study due to death from COVID 19 as entered on the AE log. Please ensure End of Study/ Study discontinuation form is completed as required and reason for discontinuation is specified. ' (Site from DM).	(b) (4), (b) (6)	18 Apr 2021 19:27:36
User signature succeeded.	Thea Marie Cordero (b) (4)	22 Mar 2021 15:17:26
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:10:55
User entered 'Yes (Y)'	Sandra Francisco (b) (4) (b) (4)	09 Mar 2021 23:42:24

US3862141
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:07:51
AEID

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:17:26
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:11:03
Reviewed for Safety.		10 Mar 2021 15:05:29
User entered 'USA-US121-2021-mRNA-1273-P301000004'	System	10 Mar 2021 15:04:46
User entered 'New'	(b) (4), (b) (6)	10 Mar 2021 15:04:46

US3862141
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:07:51
Adverse event

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:17:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:11:04
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Ventricular arrhythmias and cardiac arrest, PT: Cardio-respiratory arrest, LLT: Cardiopulmonary arrest - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Mar 2021 23:46:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Mar 2021 23:46:42
Data point term sent to Coder	System	09 Mar 2021 23:46:08
User entered 'cardiopulmonary arrest'	Sandra Francisco (b) (4) (b) (4)	09 Mar 2021 23:45:33

US3862141
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:07:51
Was this a medically-attended AE?

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:17:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:11:08
User entered 'Yes (Y)'	Sandra Francisco (b) (4) (b) (4)	09 Mar 2021 23:45:33

FDA-CBER-2022-1614-3767076

US3862141
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:07:51
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	22 Mar 2021 15:17:26
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:11:09
User entered 'No (N)'	Sandra Francisco (b) (4) (b) (4)	09 Mar 2021 23:45:33

FDA-CBER-2022-1614-3767077

US3862141
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:07:51
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	22 Mar 2021 15:17:26
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:11:12
User closed query 'PV Query Urgent: Is this an event of positive Covid-19? If yes, please update event term to Covid-19 and add results under Covid Diagnostic Test in the Covid-19 Assessments tab. If no, please change answer to No. ' (Site from Safety).		18 Mar 2021 14:34:23
Query 'PV Query Urgent: Is this an event of positive Covid-19? If yes, please update event term to Covid-19 and add results under Covid Diagnostic Test in the Covid-19 Assessments tab. If no, please change answer to No. ' answered with 'ANSWER TO SECTION CHANGED TO NO' (Site from Safety).	Thea Marie Cordero (b) (4)	17 Mar 2021 16:29:13
User entered 'No (N)' reason for change: New Information	Thea Marie Cordero (b) (4)	17 Mar 2021 16:28:26
User opened query 'PV Query Urgent: Is this an event of positive Covid-19? If yes, please update event term to Covid-19 and add results under Covid Diagnostic Test in the Covid-19 Assessments tab. If no, please change answer to No. ' (Site from Safety).	(b) (4), (b) (6)	10 Mar 2021 00:06:23
User entered 'Yes (Y)'	Sandra Francisco (b) (4) (b) (4)	09 Mar 2021 23:45:33

FDA-CBER-2022-1614-3767078

US3862141
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:07:51
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	22 Mar 2021 15:17:26
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:11:14
User entered '09 Mar 2021'	Sandra Francisco (b) (4) (b) (4)	09 Mar 2021 23:45:33

FDA-CBER-2022-1614-3767079

US3862141
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:07:51
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	22 Mar 2021 15:17:26
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:11:16
User entered empty.	Sandra Francisco (b) (4) (b) (4)	09 Mar 2021 23:45:33

FDA-CBER-2022-1614-3767080

US3862141
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:07:51
AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	09 Mar 2021 23:45:33

US3862141
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:07:51
Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:05:23
User signature succeeded.	Thea Marie Cordero (b) (4)	22 Mar 2021 15:17:26
User entered 'No (N)' reason for change: New Information	Thea Marie Cordero (b) (4)	17 Mar 2021 16:33:19
User entered 'Yes (Y)'	Sandra Francisco (b) (4) (b) (4)	09 Mar 2021 23:45:33

FDA-CBER-2022-1614-3767082

US3862141
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:07:51
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:05:25
User signature succeeded.	Thea Marie Cordero (b) (4)	22 Mar 2021 15:17:26
User entered '09 Mar 2021' reason for change: Data Entry Error	Sandra Francisco (b) (4) (b) (4)	19 Mar 2021 13:20:46
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' (Site from Safety).	(b) (4), (b) (6)	18 Mar 2021 14:34:31
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' answered with 'SUBJECT PASSED AWAY ON 09 MAR 2021' (Site from Safety).	Thea Marie Cordero (b) (4)	17 Mar 2021 16:40:44
User entered '9 Mar 2021' reason for change: New Information	Thea Marie Cordero (b) (4)	17 Mar 2021 16:33:19
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' (Site from Safety).	(b) (4), (b) (6)	16 Mar 2021 13:05:12
User entered empty.	Sandra Francisco (b) (4) (b) (4)	09 Mar 2021 23:45:33

FDA-CBER-2022-1614-3767083

US3862141
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:07:51
End time *(00:00-23:59)*

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:17:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:11:20
User entered empty.	Sandra Francisco (b) (4) (b) (4)	09 Mar 2021 23:45:33

US3862141
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:07:51
AE End Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	09 Mar 2021 23:45:33

US3862141
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:07:51
Severity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:39:44
User closed query 'Please update to Grade 5 - Death since this resulted in death. Please ensure source is updated as well.' (Site from CRA).		20 Apr 2021 15:39:40
Query 'Please update to Grade 5 - Death since this resulted in death. Please ensure source is updated as well.' answered with 'WILL REMAIN AS GRADE 4, NO GRADE 5 SELECTION. DISCUSSED WITH MONITOR (b) (6) (Site from CRA).	Thea Marie Cordero (b) (4)	13 Apr 2021 15:33:43
User opened query 'Please update to Grade 5 - Death since this resulted in death. Please ensure source is updated as well.' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 19:05:53
User signature succeeded.	Thea Marie Cordero (b) (4)	22 Mar 2021 15:17:26
User entered 'Grade 4 (Grade 4)'	Sandra Francisco (b) (4) (b) (4)	09 Mar 2021 23:45:33

FDA-CBER-2022-1614-3767086

US3862141
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:07:51
Is the adverse event serious?

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:17:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:11:45
User entered 'Yes (Y)'	Sandra Francisco (b) (4) (b) (4)	09 Mar 2021 23:45:33

FDA-CBER-2022-1614-3767087

US3862141
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:07:51
Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:06:03
User signature succeeded.	Thea Marie Cordero (b) (4)	22 Mar 2021 15:17:26
User entered '1' reason for change: New Information	Thea Marie Cordero (b) (4)	17 Mar 2021 16:33:19
User entered '0'	Sandra Francisco (b) (4) (b) (4)	09 Mar 2021 23:45:33

US3862141
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:07:51
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:17:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:11:49
User entered '1'	Sandra Francisco (b) (4) (b) (4)	09 Mar 2021 23:45:33

FDA-CBER-2022-1614-3767089

US3862141
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:07:51
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:17:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:11:50
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	17 Mar 2021 16:33:19
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System).	System	17 Mar 2021 16:33:19
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	09 Mar 2021 23:45:33
User entered '1'	Sandra Francisco (b) (4) (b) (4)	09 Mar 2021 23:45:33

FDA-CBER-2022-1614-3767090

US3862141
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:07:51
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	22 Mar 2021 15:17:26
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:11:52
User entered '09 Mar 2021'	Sandra Francisco (b) (4) (b) (4)	09 Mar 2021 23:45:33

FDA-CBER-2022-1614-3767091

US3862141
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:07:51
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:06:12
User signature succeeded.	Thea Marie Cordero (b) (4)	22 Mar 2021 15:17:26
User entered '09 Mar 2021' reason for change: New Information	Sandra Francisco (b) (4) (b) (4)	19 Mar 2021 13:20:46
User closed query 'PV Query: Please provide the hospital discharge date when available. ' (Site from Safety).	(b) (4), (b) (6)	18 Mar 2021 14:34:35
Query 'PV Query: Please provide the hospital discharge date when available. ' answered with 'SUBJECT PASSED AWAY ON 09 MAR 2021' (Site from Safety).	Thea Marie Cordero (b) (4)	17 Mar 2021 16:34:01
User entered '9 Mar 2021' reason for change: New Information	Thea Marie Cordero (b) (4)	17 Mar 2021 16:33:19
User opened query 'PV Query: Please provide the hospital discharge date when available. ' (Site from Safety).	(b) (4), (b) (6)	16 Mar 2021 13:05:24
User entered empty.	Sandra Francisco (b) (4) (b) (4)	09 Mar 2021 23:45:33

US3862141
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:07:51
Admitted to ICU?

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	22 Mar 2021 15:17:26
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:12:00
User entered 'Yes (Y)'	Sandra Francisco (b) (4) (b) (4)	09 Mar 2021 23:45:33

US3862141
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:07:51
Number of Days in ICU

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:06:16
User closed query 'Per CDM: Site response noted. Please complete when available and then route back to DM. Thank you.' (Site from DM).		01 Apr 2021 13:08:56
User signature succeeded.	Thea Marie Cordero (b) (4)	22 Mar 2021 15:17:26
Query 'Per CDM: Site response noted. Please complete when available and then route back to DM. Thank you.' answered with 'ANSWER TO SECTION WAS UPDATED TO 1 DAY' (Site from DM).	Thea Marie Cordero (b) (4)	17 Mar 2021 16:40:05
User entered '1' reason for change: New Information	Thea Marie Cordero (b) (4)	17 Mar 2021 16:33:19
User closed query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	11 Mar 2021 11:43:31
User opened query 'Per CDM: Site response noted. Please complete when available and then route back to DM. Thank you.' (Site from DM).		11 Mar 2021 11:43:30
Query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' answered with 'Data pending medical records. ' (Site from System).	Sandra Francisco (b) (4) (b) (4)	09 Mar 2021 23:57:43
User opened query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' (Site from System).	System	09 Mar 2021 23:45:33
User entered empty.	Sandra Francisco (b) (4) (b) (4)	09 Mar 2021 23:45:33

US3862141
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:07:51
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	22 Mar 2021 15:17:26
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:12:05
User entered '0'	Sandra Francisco (b) (4) (b) (4)	09 Mar 2021 23:45:33

US3862141
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:07:51
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	22 Mar 2021 15:17:26
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:12:07
User entered '0'	Sandra Francisco (b) (4) (b) (4)	09 Mar 2021 23:45:33

FDA-CBER-2022-1614-3767096

US3862141
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:07:51
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	22 Mar 2021 15:17:26
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:12:09
User entered '0'	Sandra Francisco (b) (4) (b) (4)	09 Mar 2021 23:45:33

US3862141
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:07:51
Relationship to investigational product

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:17:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:12:12
User entered 'Not Related (NOT RELATED)'	Sandra Francisco (b) (4) (b) (4)	09 Mar 2021 23:45:33

US3862141
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:07:51
Relationship to Study Procedure

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	22 Mar 2021 15:17:26
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:12:13
User entered 'Not Related (NOT RELATED)'	Sandra Francisco (b) (4) (b) (4)	09 Mar 2021 23:45:33

FDA-CBER-2022-1614-3767099

US3862141
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:07:51
Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:17:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:12:15
User entered 'Not Applicable (NOT APPLICABLE)'	Sandra Francisco (b) (4) (b) (4)	09 Mar 2021 23:45:33

US3862141
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:07:51
None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:06:30
User signature succeeded.	Thea Marie Cordero (b) (4)	22 Mar 2021 15:17:26
User entered '0' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	17 Mar 2021 16:33:19
User entered '1'	Sandra Francisco (b) (4) (b) (4)	09 Mar 2021 23:45:33

US3862141
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:07:51
Concomitant Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:06:32
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). Please leave query unanswered until information is available. If no treatment was provided, please state so.' (Site from Safety).		30 Mar 2021 14:53:45
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). Please leave query unanswered until information is available. If no treatment was provided, please state so.' answered with 'INFORMATION UNAVAILABLE. PENDING MEDICAL RECORDS' (Site from Safety).	Thea Marie Cordero (b) (4)	29 Mar 2021 19:57:27
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). Please leave query unanswered until information is available. If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	29 Mar 2021 18:05:50
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	29 Mar 2021 18:05:50

US3862141
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:07:51
Concomitant Medication

Audit	User	Time (GMT)
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'Information unavailable. Awaiting medical records.' (Site from Safety).	Thea Marie Cordero (b) (4)	26 Mar 2021 22:56:15
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	25 Mar 2021 14:13:44
User signature succeeded.	Thea Marie Cordero (b) (4)	22 Mar 2021 15:17:26
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' (Site from Safety).	(b) (4), (b) (6)	18 Mar 2021 14:34:46
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' answered with 'PENDING MEDICAL RECORDS' (Site from Safety).	Thea Marie Cordero (b) (4)	17 Mar 2021 16:34:29
User entered '1' reason for change: New Information	Thea Marie Cordero (b) (4)	17 Mar 2021 16:33:19

FDA-CBER-2022-1614-3767103

US3862141
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:07:51
Concomitant Medication

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' (Site from Safety).	(b) (4), (b) (6)	16 Mar 2021 13:04:28
User entered '0'	Sandra Francisco (b) (4) (b) (4)	09 Mar 2021 23:45:33

FDA-CBER-2022-1614-3767104

US3862141
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:07:51
Concomitant Procedure

Audit	User	Time (GMT)
DataPoint Verified. User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until information is available. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 19:06:34 30 Mar 2021 14:53:59
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until information is available. If no results are available, please confirm in your response.' answered with 'INFORMATION UNAVAILABLE. PENDING MEDICAL RECORDS' (Site from Safety).	Thea Marie Cordero (b) (4)	29 Mar 2021 19:57:37
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until information is available. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	29 Mar 2021 18:06:00
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	29 Mar 2021 18:06:00

US3862141
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:07:51
Concomitant Procedure

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'Information unavailable. Awaiting medical records.' (Site from Safety).	Thea Marie Cordero (b) (4)	26 Mar 2021 22:56:17
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	25 Mar 2021 14:14:02
User signature succeeded.	Thea Marie Cordero (b) (4)	22 Mar 2021 15:17:26
User entered '1' reason for change: New Information	Thea Marie Cordero (b) (4)	17 Mar 2021 16:33:19
User entered '0'	Sandra Francisco (b) (4) (b) (4)	09 Mar 2021 23:45:33

US3862141
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:07:51
Outcome

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:06:45
User closed query 'PV Query: Please provide autopsy results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342, if performed. Please leave query unanswered until information is available. If not performed, please state so.' (Site from Safety).		30 Mar 2021 14:53:56
User closed query 'PV Query: Please provide/confirm the cause of death. Please leave query unanswered until information is available. ' (Site from Safety).	(b) (4), (b) (6)	30 Mar 2021 14:53:49
Query 'PV Query: Please provide autopsy results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342, if performed. Please leave query unanswered until information is available. If not performed, please state so.' answered with 'INFORMATION UNAVAILABLE. PENDING MEDICAL RECORDS' (Site from Safety).	Thea Marie Cordero (b) (4)	29 Mar 2021 19:57:55
Query 'PV Query: Please provide/confirm the cause of death. Please leave query unanswered until information is available. ' answered with 'INFORMATION UNAVAILABLE. PENDING MEDICAL RECORDS' (Site from Safety).	Thea Marie Cordero (b) (4)	29 Mar 2021 19:57:47
User opened query 'PV Query: Please provide autopsy results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342, if performed. Please leave query unanswered until information is available. If not performed, please state so.' (Site from Safety).	(b) (4), (b) (6)	29 Mar 2021 18:06:18
User closed query 'PV Query: Please provide autopsy results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342, if performed. If not performed, please state so.' (Site from Safety).	(b) (4), (b) (6)	29 Mar 2021 18:06:18
User opened query 'PV Query: Please provide/confirm the cause of death. Please leave query unanswered until information is available. ' (Site from Safety).	(b) (4), (b) (6)	29 Mar 2021 18:06:12
User closed query 'PV Query: Please provide/confirm the cause of death.' (Site from Safety).	(b) (4), (b) (6)	29 Mar 2021 18:06:12

US3862141
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:07:51
Outcome

Audit	User	Time (GMT)
Query 'PV Query: Please provide autopsy results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342, if performed. If not performed, please state so.' answered with 'Information unavailable. Awaiting medical records.' (Site from Safety).	Thea Marie Cordero (b) (4)	26 Mar 2021 22:56:28
Query 'PV Query: Please provide/confirm the cause of death.' answered with 'Information unavailable. Awaiting medical records.' (Site from Safety).	Thea Marie Cordero (b) (4)	26 Mar 2021 22:56:19
User opened query 'PV Query: Please provide autopsy results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342, if performed. If not performed, please state so.' (Site from Safety).	(b) (4), (b) (6)	25 Mar 2021 14:14:55
User opened query 'PV Query: Please provide/confirm the cause of death.' (Site from Safety).		25 Mar 2021 14:14:38
User signature succeeded.	Thea Marie Cordero (b) (4)	22 Mar 2021 15:17:26
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved' (Site from Safety).	(b) (4), (b) (6)	18 Mar 2021 14:34:51
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved' answered with 'FINAL OUTCOME: SUBJECT PASSED AWAY ON 09 MAR 2021' (Site from Safety).	Thea Marie Cordero (b) (4)	17 Mar 2021 16:36:34
User entered 'Fatal (FATAL)' reason for change: New Information	Thea Marie Cordero (b) (4)	17 Mar 2021 16:33:19
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved' (Site from Safety).	(b) (4), (b) (6)	16 Mar 2021 13:04:53
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Sandra Francisco (b) (4) (b) (4)	09 Mar 2021 23:45:33

US3862141
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:07:51
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	22 Mar 2021 15:17:26
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:15:04
User entered empty.	Sandra Francisco (b) (4) (b) (4)	09 Mar 2021 23:45:33

US3862141
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:07:51
Narrative

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide autopsy results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342, if performed. Please leave query unanswered until information is available. If not performed, please state so' (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 22:15:24
Query 'PV Query: Please provide autopsy results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342, if performed. Please leave query unanswered until information is available. If not performed, please state so. Revised 29 Mar 2021 PV Query: Please provide autopsy results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342, if performed. If not performed, please state so.' canceled (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 22:15:20
User opened query 'Per CDM RQ: Kindly update 'Per DM CLR: Narrative indicates that subject "MECHANICALLY VENTILATED AND SEDATED." However, this information is not recorded in the appropriate eCRF pages. Please review and ensure that these are captured in the appropriate eCRF. Thank you!' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 02:56:58
User closed query 'Per DM CLR: Narrative indicates that subject "MECHANICALLY VENTILATED AND SEDATED." However, this information is not recorded in the appropriate eCRF pages. Please review and ensure that these are captured in the appropriate eCRF. ' (Site from DM).		23 Apr 2021 02:53:51
DataPoint Verified.		12 Apr 2021 19:07:53

FDA-CBER-2022-1614-3767110

US3862141
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:07:51
Narrative

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). Please leave query unanswered until information is available. If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	05 Apr 2021 21:32:52
User opened query 'PV Query: Please provide autopsy results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342, if performed. Please leave query unanswered until information is available. If not performed, please state so. Revised 29 Mar 2021 PV Query: Please provide autopsy results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342, if performed. If not performed, please state so.' (Site from Safety).	(b) (4), (b) (6)	05 Apr 2021 21:29:31
User opened query 'PV Query: Please provide/confirm the cause of death. Please leave query unanswered until information is available. ' (Site from Safety).	(b) (4), (b) (6)	05 Apr 2021 21:29:07
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until information is available. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	05 Apr 2021 21:28:44

US3862141
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:07:51
Narrative

Audit	User	Time (GMT)
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). Please leave query unanswered until information is available. If no treatment was provided, please state so. Revised 29 Mar 2021 PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' canceled (Site from Safety).	(b) (4), (b) (6)	05 Apr 2021 21:28:26
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). Please leave query unanswered until information is available. If no treatment was provided, please state so. Revised 29 Mar 2021 PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	05 Apr 2021 21:28:15
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.?Please leave query unanswered until information is available. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	05 Apr 2021 21:28:03

US3862141
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:07:51
Narrative

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide autopsy results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342, if performed. Please leave query unanswered until information is available. If not performed, please state so.' (Site from Safety).	(b) (4), (b) (6)	05 Apr 2021 15:32:20
User closed query 'PV Query: Please provide/confirm the cause of death. Please leave query unanswered until information is available. ' (Site from Safety).		05 Apr 2021 15:32:14
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until information is available. If no results are available, please confirm in your response.' (Site from Safety).		05 Apr 2021 15:32:08
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). Please leave query unanswered until information is available. If no treatment was provided, please state so. ' (Site from Safety).	(b) (4), (b) (6)	05 Apr 2021 15:32:04
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.?Please leave query unanswered until information is available. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	05 Apr 2021 15:31:56
Query 'PV Query: Please provide autopsy results wit patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342, if performed. Please leave query unanswered until information is available. If not performed, please state so.' answered with 'pending medical records' (Site from Safety).		02 Apr 2021 18:52:10

US3862141
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:07:51
Narrative

Audit	User	Time (GMT)
Query 'PV Query: Please provide/confirm the cause of death. Please leave query unanswered until information is available. ' answered with 'pending medical records' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 18:52:07
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until information is available. If no results are available, please confirm in your response.' answered with 'pending medical records' (Site from Safety).		02 Apr 2021 18:52:04
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). Please leave query unanswered until information is available. If no treatment was provided, please state so. ' answered with 'pending medical records' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 18:52:02
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.?Please leave query unanswered until information is available. If not done, please state so.' answered with 'pending medical records' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 18:51:59
User opened query 'PV Query: Please provide autopsy results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342, if performed. Please leave quer unanswered until information is available. If not performed, please state so.' (Site from Safety).		02 Apr 2021 18:46:27
User opened query 'PV Query: Please provide/confirm the cause of death. Please leave query unanswered until information is available. ' (Site from Safety).		02 Apr 2021 18:46:16

US3862141
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:07:51
Narrative

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until information is available. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 18:46:01
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). Please leave query unanswered until information is available. If no treatment was provided, please state so. ' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 18:45:41
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.?Please leave query unanswered until information is available. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 18:45:26
User closed query 'PV Query: Please provide/confirm the cause of death. Please leave query unanswered until information is available. ' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 16:10:34
User closed query 'PV Query: Please provide autopsy results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342, if performed. Please leave query unanswered until information is available. If not performed, please state so.' (Site from Safety).		02 Apr 2021 16:10:32

US3862141
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:07:51
Narrative

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until information is available. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 16:10:23
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). Please leave query unanswered until information is available. If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 16:10:20
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.?Please leave query unanswered until information is available. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 16:10:16
Query 'PV Query: Please provide autopsy results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342, if performed. Please leave query unanswered until information is available. If not performed, please state so.' answered with 'pending medical records ' (Site from Safety).	(b) (4), (b) (6)	01 Apr 2021 20:00:32
Query 'PV Query: Please provide/confirm the cause of death. Please leave query unanswered until information is available. ' answered with 'pending medical records ' (Site from Safety).	(b) (4), (b) (6)	01 Apr 2021 20:00:27

US3862141
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:07:51
Narrative

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until information is available. If no results are available, please confirm in your response.' answered with 'pending medical records ' (Site from Safety).	(b) (4), (b) (6)	01 Apr 2021 20:00:25
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). Please leave query unanswered until information is available. If no treatment was provided, please state so.' answered with 'pending medical records ' (Site from Safety).	(b) (4), (b) (6)	01 Apr 2021 20:00:22
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.?Please leave query unanswered until information is available. If not done, please state so.' answered with 'pending medical records ' (Site from Safety).	(b) (4), (b) (6)	01 Apr 2021 20:00:18
User opened query 'PV Query: Please provide autopsy results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342, if performed. Please leave query unanswered until information is available. If not performed, please state so.' (Site from Safety).	(b) (4), (b) (6)	01 Apr 2021 18:21:47
User closed query 'PV Query: Please provide autopsy results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342, if performed. Please leave query unanswered until information is available. If not performed, please state so.' (Site from Safety).		01 Apr 2021 18:21:47
User opened query 'PV Query: Please provide/confirm the cause of death. Please leave query unanswered until information is available. ' (Site from Safety).		01 Apr 2021 18:19:04

US3862141
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:07:51
Narrative

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide/confirm the cause of death. Please leave query unanswered until information is available. ' (Site from Safety).	(b) (4), (b) (6)	01 Apr 2021 18:19:04
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until information is available. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	01 Apr 2021 18:18:50
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until information is available. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	01 Apr 2021 18:18:50
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). Please leave query unanswered until information is available. If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	01 Apr 2021 18:17:35
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). Please leave query unanswered until information is available. If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	01 Apr 2021 18:17:35

US3862141
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:07:51
Narrative

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.?Please leave query unanswered until information is available. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	01 Apr 2021 18:15:12
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.?Please leave query unanswered until information is available. If not done, please state so.' (Site from Safety).		01 Apr 2021 18:15:12
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.?Please leave query unanswered until information is available. If not done, please state so.' answered with 'INFORMATION UNAVAILABLE. AWAITING MEDICAL RECORDS' (Site from Safety).		31 Mar 2021 18:05:41
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). Please leave query unanswered until information is available. If no treatment was provided, please state so.' answered with 'INFORMATION UNAVAILABLE. AWAITING MEDICAL RECORDS' (Site from Safety).	(b) (4), (b) (6)	31 Mar 2021 18:05:37
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until information is available. If no results are available, please confirm in your response.' answered with 'INFORMATION UNAVAILABLE. AWAITING MEDICAL RECORDS' (Site from Safety).		31 Mar 2021 18:05:33

US3862141
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:07:51
Narrative

Audit	User	Time (GMT)
Query 'PV Query: Please provide/confirm the cause of death. Please leave query unanswered until information is available. ' answered with 'INFORMATION UNAVAILABLE. AWAITING MEDICAL RECORDS' (Site from Safety).	(b) (4), (b) (6)	31 Mar 2021 18:05:30
Query 'PV Query: Please provide autopsy results wit patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342, if performed. Please leave query unanswered until information is available. If not performed, please state so.' answered with 'INFORMATION UNAVAILABLE. AWAITING MEDICAL RECORDS' (Site from Safety).		31 Mar 2021 18:05:26
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.?Please leave query unanswered until information is available. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	31 Mar 2021 17:08:37
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). Please leave query unanswered until information is available. If no treatment was provided, please state so.' (Site from Safety).		31 Mar 2021 17:08:28
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until information is available. If no results are available, please confirm in your response.' (Site from Safety).		31 Mar 2021 17:08:17
User opened query 'PV Query: Please provide/confirm the cause of death. Please leave query unanswered until information is available. ' (Site from Safety).		31 Mar 2021 17:08:04

US3862141
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:07:51
Narrative

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide autopsy results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342, if performed. Please leave query unanswered until information is available. If not performed, please state so.' (Site from Safety).	(b) (4), (b) (6)	31 Mar 2021 17:07:50
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until information is available. If no results are available, please confirm in your response.' (Site from Safety).		31 Mar 2021 13:28:29
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). Please leave query unanswered until information is available. If no treatment was provided, please state so.' (Site from Safety).		31 Mar 2021 13:28:25
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.?Please leave query unanswered until information is available. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	31 Mar 2021 13:28:21
User closed query 'PV Query: Please provide autopsy results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342, if performed. Please leave query unanswered until information is available. If not performed, please state so.' (Site from Safety).		31 Mar 2021 13:28:18
User closed query 'PV Query: Please provide/confirm the cause of death. Please leave query unanswered until information is available. ' (Site from Safety).		31 Mar 2021 13:28:15

US3862141
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:07:51
Narrative

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until information is available. If no results are available, please confirm in your response.' answered with 'INFORMATION UNAVAILABLE. AWAITING MEDICAL RECORDS' (Site from Safety).	Thea Marie Cordero (b) (4)	30 Mar 2021 23:19:40
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). Please leave query unanswered until information is available. If no treatment was provided, please state so.' answered with 'INFORMATION UNAVAILABLE. AWAITING MEDICAL RECORDS' (Site from Safety).	Thea Marie Cordero (b) (4)	30 Mar 2021 23:19:35
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.?Please leave query unanswered until information is available. If not done, please state so.' answered with 'INFORMATION UNAVAILABLE. AWAITING MEDICAL RECORDS' (Site from Safety).	Thea Marie Cordero (b) (4)	30 Mar 2021 23:19:28
Query 'PV Query: Please provide autopsy results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342, if performed. Please leave query unanswered until information is available. If not performed, please state so.' answered with 'INFORMATION UNAVAILABLE. AWAITING MEDICAL RECORDS' (Site from Safety).	Thea Marie Cordero (b) (4)	30 Mar 2021 23:19:20

US3862141
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:07:51
Narrative

Audit	User	Time (GMT)
Query 'PV Query: Please provide/confirm the cause of death. Please leave query unanswered until information is available. ' answered with 'INFORMATION UNAVAILABLE. AWAITING MEDICAL RECORDS' (Site from Safety).	Thea Marie Cordero (b) (4)	30 Mar 2021 23:19:10
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until information is available. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	30 Mar 2021 17:06:01
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). Please leave query unanswered until information is available. If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	30 Mar 2021 17:05:41
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.?Please leave query unanswered until information is available. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	30 Mar 2021 17:05:29
User opened query 'PV Query: Please provide autopsy results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342, if performed. Please leave query unanswered until information is available. If not performed, please state so.' (Site from Safety).	(b) (4), (b) (6)	30 Mar 2021 17:05:06
User opened query 'PV Query: Please provide/confirm the cause of death. Please leave query unanswered until information is available. ' (Site from Safety).	(b) (4), (b) (6)	30 Mar 2021 17:04:53

US3862141
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:07:51
Narrative

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.?Please leave query unanswered until information is available. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	30 Mar 2021 14:54:02
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.?Please leave query unanswered until information is available. If not done, please state so.' answered with 'INFORMATION UNAVAILABLE. PENDING MEDICAL RECORDS' (Site from Safety).	Thea Marie Cordero (b) (4)	29 Mar 2021 19:58:07
Query 'Per DM CLR: Narrative indicates that subject "MECHANICALLY VENTILATED AND SEDATED." However, this information is not recorded in the appropriate eCRF pages. Please review and ensure that these are captured in the appropriate eCRF. ' answered with 'INFORMATION UNAVAILABLE. PENDING MEDICAL RECORDS' (Site from DM).	Thea Marie Cordero (b) (4)	29 Mar 2021 19:58:02
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.?Please leave query unanswered until information is available. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	29 Mar 2021 18:05:38
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).		29 Mar 2021 18:05:38
User opened query 'Per DM CLR: Narrative indicates that subject "MECHANICALLY VENTILATED AND SEDATED." However, this information is not recorded in the appropriate eCRF pages. Please review and ensure that these are captured in the appropriate eCRF. ' (Site from DM).		27 Mar 2021 06:38:10

US3862141
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:07:51
Narrative

Audit	User	Time (GMT)
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' answered with 'Information unavailable. Awaiting medical records.' (Site from Safety).	Thea Marie Cordero (b) (4)	26 Mar 2021 22:56:31
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	25 Mar 2021 14:13:05
User signature succeeded.	Thea Marie Cordero (b) (4)	22 Mar 2021 15:17:26
DataPoint Un-verified.	Thea Marie Cordero (b) (4)	19 Mar 2021 22:20:22

US3862141
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:07:51
Narrative

Audit	User	Time (GMT)
User entered 'CARDIOPULMONARY ARREST RELATED TO UNDERLYING MEDICAL HISTORY (CAD, ATRIAL FIBRILLATION REQUIRING ICD INSERTION) NARRATIVE: PI CALLED SUBJECT'S FAMILY. THE SUBJECT HAD A LEAK IN THE HOUSE AND RAN UPSTAIRS QUICKLY TO CHECK. AFTER THE RAPID MOVEMENT HIS HEART WAS RACING AND COLLAPSED LOSING CONSCIOUSNESS. HE BRIEFLY REGAINED CONSCIOUSNESS AND LOST IT AGAIN. NO OTHER COMPLAINTS, SEIZURE ACTIVITY, HOLDING CHEST. IN THE ER, HE HAS FOUND TO BE IN VENTRICULAR FIBRILLATION, HE WAS BROUGHT BACK IN INTO RHYTHM (SINUS?) AND ADMITTED TO MICU. HE IS CURRENTLY MECHANICALLY VENTILATED AND SEDATED. SITE WILL FOLLOW UP WITH SUBJECT AND FAMILY MEMBERS FOR HEALTH UPDATES AND REQUEST MEDICAL RECORDS. 17 MAR 2021: DAUGHTER IN LAW WAS CONTACTED AND REPORTED THAT SUBJECT HAD ANOTHER CARDIOPULMONARY ARREST AND PASSED AWAY ON THE SAME DAY 09 MAR 2021. MEDICAL RECORDS WILL BE REQUESTED 19MAR2021: Medical records were requested today, 19MAR2021' reason for change: New Information	Thea Marie Cordero (b) (4)	19 Mar 2021 22:20:22
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:14:55
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. ' (Site from Safety).		18 Mar 2021 14:35:20
User closed query 'PV Query: Please clarify this sentence: 'No other complaints, seizure activity, holding chest.' ' (Site from Safety).	(b) (4), (b) (6)	18 Mar 2021 14:35:18

US3862141
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:07:51
Narrative

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so. ' (Site from Safety).	(b) (4), (b) (6)	18 Mar 2021 14:34:55
User entered 'CARDIOPULMONARY ARREST RELATED TO UNDERLYING MEDICAL HISTORY (CAD, ATRIAL FIBRILLATION REQUIRING ICD INSERTION) NARRATIVE: PI CALLED SUBJECT'S FAMILY. THE SUBJECT HAD A LEAK IN THE HOUSE AND RAN UPSTAIRS QUICKLY TO CHECK. AFTER THE RAPID MOVEMENT HIS HEART WAS RACING AND COLLAPSED LOSING CONSCIOUSNESS. HE BRIEFLY REGAINED CONSCIOUSNESS AND LOST IT AGAIN. NO OTHER COMPLAINTS, SEIZURE ACTIVITY, HOLDING CHEST. IN THE ER, HE HAS FOUND TO BE IN VENTRICULAR FIBRILLATION, HE WAS BROUGHT BACK IN INTO RHYTHM (SINUS?) AND ADMITTED TO MICU. HE IS CURRENTLY MECHANICALLY VENTILATED AND SEDATED. SITE WILL FOLLOW UP WITH SUBJECT AND FAMILY MEMBERS FOR HEALTH UPDATES AND REQUEST MEDICAL RECORDS. 17 MAR 2021: DAUGHTER IN LAW WAS CONTACTED AND REPORTED THAT SUBJECT HAD ANOTHER CARDIOPULMONARY ARREST AND PASSED AWAY ON THE SAME DAY 09 MAR 2021. MEDICAL RECORDS WILL BE REQUESTED' reason for change: New Information	Thea Marie Cordero (b) (4)	17 Mar 2021 16:39:03
Query 'PV Query: Please clarify this sentence: 'No other complaints, seizure activity, holding chest.' ' answered with 'WILL BE CLARIFIED ONCE MEDICAL RECORDS ARE AVAILABLE' (Site from Safety).	Thea Marie Cordero (b) (4)	17 Mar 2021 16:36:01

US3862141
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:07:51
Narrative

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. ' answered with 'PENDING MEDICAL RECORDS' (Site from Safety).	Thea Marie Cordero (b) (4)	17 Mar 2021 16:35:04
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so. ' answered with 'PENDING MEDICAL RECORDS' (Site from Safety).	Thea Marie Cordero (b) (4)	17 Mar 2021 16:34:56
User opened query 'PV Query: Please clarify this sentence: 'No other complaints, seizure activity, holding chest.' ' (Site from Safety).	(b) (4), (b) (6)	16 Mar 2021 13:04:12
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. ' (Site from Safety).		16 Mar 2021 13:04:01
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so. ' (Site from Safety).		16 Mar 2021 13:03:38
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	09 Mar 2021 23:56:49
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	09 Mar 2021 23:56:49

US3862141
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:07:51
Narrative

Audit	User	Time (GMT)
User entered 'Cardiopulmonary arrest related to underlying medical history (CAD, Atrial fibrillation requiring ICD insertion) Narrative: PI called subject's family. The subject had a leak in the house and ran upstairs quickly to check. After the rapid movement his heart was racing and collapsed losing consciousness. He briefly regained consciousness and lost it again. No other complaints, seizure activity, holding chest. In the ER, he has found to be in ventricular fibrillation, he was brought back in into rhythm (sinus?) and admitted to MICU. He is currently mechanically ventilated and sedated. Site will follow up with subject and family members for health updates and request medical records.' reason for change: Data Entry Error	Sandra Francisco (b) (4) (b) (4)	09 Mar 2021 23:56:49
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	09 Mar 2021 23:45:33
User entered empty.	Sandra Francisco (b) (4) (b) (4)	09 Mar 2021 23:45:33

FDA-CBER-2022-1614-3767129

US3862141
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:07:51
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '1'	System	09 Mar 2021 23:45:33

US3862141
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:07:51
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	09 Mar 2021 23:45:33

US3862141
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 10:07:51
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	09 Mar 2021 23:45:33

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination Summary
Generated On: 10 Jun 2021 10:07:51
Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:35:03
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'Yes (Y)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:42:35

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 10:07:51
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Sep 2020 15:59:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Sep 2020 15:59:51
Data point term sent to Coder	System	14 Sep 2020 14:44:12
User entered 'insulin'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:43:51

FDA-CBER-2022-1614-3767134

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 10:07:51
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'No (N)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:43:51

FDA-CBER-2022-1614-3767135

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 10:07:51
Indication

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'diabetes mellitus type 2'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:43:51

FDA-CBER-2022-1614-3767136

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 10:07:51
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:26:25
User closed query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 10 IU, etc) instead of injection count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Nov 2020 13:37:38
Query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 10 IU, etc) instead of injection count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate' answered with 'updated' (Site from DM).	Shetel Anassi (b) (4) (b) (4)	09 Nov 2020 20:55:02
User entered '2' reason for change: Data Entry Error	Shetel Anassi (b) (4)	09 Nov 2020 20:54:43
User opened query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 10 IU, etc) instead of injection count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Nov 2020 10:24:16
Query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 10 IU, etc) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' canceled (Site from DM).	(b) (4), (b) (6)	08 Nov 2020 10:24:02
User opened query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 10 IU, etc) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Nov 2020 10:23:47
User entered 'two'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:43:51

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 10:07:51
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'Other (OTHER)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:43:51

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 10:07:51
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'UNITs' reason for change: Data Entry Error	Shetel Anassi (b) (4) (b) (4)	09 Nov 2020 20:54:53
User entered 'unites' reason for change: Data Entry Error	Shetel Anassi (b) (4) (b) (4)	09 Nov 2020 20:54:43
User entered 'injections'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:43:51

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 10:07:51
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'twice daily (BID)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:43:51

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 10:07:51
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered empty.	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:43:51

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 10:07:51
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'Subcutaneous (SUBCUTANEOUS)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:43:51

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 10:07:51
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered empty.	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:43:51

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 10:07:51
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'un UNK 2016'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:43:51

FDA-CBER-2022-1614-3767144

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 10:07:51
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered '0'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:43:51

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 10:07:51
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'Yes (Y)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:43:51

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 10:07:51
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered empty.	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:43:51

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 10:07:51
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'No (N)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:43:51

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 10:07:51
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '2'	System	14 Sep 2020 14:43:51

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 10:07:51
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 14:43:51

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 10:07:51
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Sep 2020 14:43:51

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 10:07:51
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Sep 2020 14:45:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Sep 2020 14:45:47
Data point term sent to Coder	System	14 Sep 2020 14:45:13
User entered 'furosemide'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:44:52

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 10:07:51
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'No (N)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:44:52

FDA-CBER-2022-1614-3767153

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 10:07:51
Indication

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'congestive heart failure'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:44:52

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 10:07:51
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered '40'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:44:52

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 10:07:51
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'mg (mg)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:44:52

FDA-CBER-2022-1614-3767156

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 10:07:51
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered empty.	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:44:52

FDA-CBER-2022-1614-3767157

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 10:07:51
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'once daily (QD)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:44:52

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 10:07:51
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered empty.	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:44:52

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 10:07:51
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'Oral (ORAL)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:44:52

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 10:07:51
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered empty.	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:44:52

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 10:07:51
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'un UNK 2004'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:44:52

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 10:07:51
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered '0'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:44:52

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 10:07:51
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'Yes (Y)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:44:52

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 10:07:51
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered empty.	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:44:52

FDA-CBER-2022-1614-3767165

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 10:07:51
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'No (N)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:44:52

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 10:07:51
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 14:44:52

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 10:07:51
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 14:44:52

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 10:07:51
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Sep 2020 14:44:52

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 10:07:51
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: CARVEDILOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Sep 2020 14:47:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Sep 2020 14:47:53
Data point term sent to Coder	System	14 Sep 2020 14:46:18
User entered 'carvedilol'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:45:54

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 10:07:51
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'No (N)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:45:54

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 10:07:51
Indication

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'congestive heart failure'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:45:54

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 10:07:51
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered '25'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:45:54

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 10:07:51
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'mg (mg)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:45:54

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 10:07:51
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered empty.	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:45:54

FDA-CBER-2022-1614-3767175

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 10:07:51
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'once daily (QD)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:45:54

FDA-CBER-2022-1614-3767176

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 10:07:51
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered empty.	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:45:54

FDA-CBER-2022-1614-3767177

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 10:07:51
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'Oral (ORAL)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:45:54

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 10:07:51
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered empty.	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:45:54

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 10:07:51
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'un UNK 2004'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:45:54

FDA-CBER-2022-1614-3767180

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 10:07:51
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered '0'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:45:54

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 10:07:51
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'Yes (Y)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:45:54

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 10:07:51
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered empty.	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:45:54

FDA-CBER-2022-1614-3767183

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 10:07:51
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'No (N)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:45:54

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 10:07:51
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 14:45:54

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 10:07:51
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 14:45:54

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Sep 2020 14:45:54

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 10:07:51
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN, PRODUCTSYNONYM: LIPITOR [ATORVASTATIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Sep 2020 14:48:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Sep 2020 14:48:41
Data point term sent to Coder	System	14 Sep 2020 14:47:22
User entered 'Lipitor'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:46:47

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 10:07:51
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'No (N)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:46:47

FDA-CBER-2022-1614-3767189

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 10:07:51
Indication

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'Coronary Artery Disease'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:46:47

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 10:07:51
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered '20'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:46:47

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 10:07:51
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'mg (mg)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:46:47

FDA-CBER-2022-1614-3767192

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 10:07:51
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered empty.	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:46:47

FDA-CBER-2022-1614-3767193

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 10:07:51
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'once daily (QD)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:46:47

FDA-CBER-2022-1614-3767194

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 10:07:51
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered empty.	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:46:47

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 10:07:51
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'Oral (ORAL)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:46:47

FDA-CBER-2022-1614-3767196

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 10:07:51
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered empty.	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:46:47

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 10:07:51
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'un UNK 2005'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:46:47

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 10:07:51
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered '0'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:46:47

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 10:07:51
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Sep 2020 14:46:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Sep 2020 14:46:53
User entered 'Yes (Y)' reason for change: Data Entry Error	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:46:53
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Sep 2020 14:46:47
User entered empty.	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:46:47

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 10:07:51
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered empty.	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:46:47

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 10:07:51
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Sep 2020 14:46:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Sep 2020 14:46:53
User entered 'No (N)' reason for change: Data Entry Error	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:46:53
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Sep 2020 14:46:47
User entered empty.	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:46:47

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 10:07:51
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 14:46:47

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 10:07:51
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 14:46:47

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 10:07:51
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Sep 2020 14:46:47

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 10:07:51
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Sep 2020 14:49:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Sep 2020 14:49:45
Data point term sent to Coder	System	14 Sep 2020 14:48:23
User entered 'levothyroxine'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:47:46

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 10:07:51
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'No (N)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:47:46

FDA-CBER-2022-1614-3767207

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 10:07:51
Indication

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'Hypothyroidism'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:47:46

FDA-CBER-2022-1614-3767208

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 10:07:51
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered '0.1'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:47:46

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 10:07:51
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'mg (mg)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:47:46

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 10:07:51
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered empty.	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:47:46

FDA-CBER-2022-1614-3767211

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 10:07:51
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'once daily (QD)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:47:46

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 10:07:51
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered empty.	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:47:46

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 10:07:51
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'Oral (ORAL)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:47:46

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 10:07:51
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered empty.	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:47:46

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 10:07:51
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'un UNK 1995'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:47:46

FDA-CBER-2022-1614-3767216

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 10:07:51
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered '0'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:47:46

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 10:07:51
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'Yes (Y)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:47:46

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 10:07:51
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered empty.	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:47:46

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 10:07:51
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'No (N)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:47:46

FDA-CBER-2022-1614-3767220

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 10:07:51
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 14:47:46

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 10:07:51
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 14:47:46

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 10:07:51
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Sep 2020 14:47:46

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 10:07:51
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 15:41:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 15:41:46
Data point term sent to Coder	System	17 Sep 2020 15:22:03
User closed query 'CDM Coding: This medication cannot be referred in the standard coding dictionary. Please verify the spelling of this medication. If spelling is correct, please enter the active ingredients in parentheses following the drug name and make your change to the reported term. Thank you.' (Site from System).	System	17 Sep 2020 15:21:35
Query 'CDM Coding: This medication cannot be referred in the standard coding dictionary. Please verify the spelling of this medication. If spelling is correct, please enter the active ingredients in parentheses following the drug name and make your change to the reported term. Thank you.' answered with 'Changed spelling and included vitamins.' (Site from System).	Carrie Kibler (b) (4) (b) (4)	17 Sep 2020 15:21:35
User entered 'NEPHRO vitamin with ascorbic acid, niacinamide, pantothenic acid, pyridoxine hydrocholride, riboflavin, thiamine mononitrate, folic acid, d-biotin, and cyanocobalamin' reason for change: Data Entry Error	Carrie Kibler (b) (4) (b) (4)	17 Sep 2020 15:21:24
Data point term sent to Coder	System	17 Sep 2020 15:16:55
User entered 'NEPHRO-vite' reason for change: Data Entry Error	Carrie Kibler (b) (4) (b) (4)	17 Sep 2020 15:16:47

US3862141

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:07:51

Name of Medication

Audit	User	Time (GMT)
User opened query 'CDM Coding: This medication cannot be referred in the standard coding dictionary. Please verify the spelling of this medication. If spelling is correct, please enter the active ingredients in parentheses following the drug name and make your change to the reported term. Thank you.' (Site from System).	Coder Import (b) (4) (b) (4)	17 Sep 2020 06:25:47
Data point term sent to Coder	System	14 Sep 2020 14:52:27
User entered 'nephrovitamin'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:51:37

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 10:07:51
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:26:25
User closed query 'Per DM CLR: Please review response to this field if this should be 'YES' as the indication specified that this is a supplement. Please update accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Nov 2020 13:37:44
Query 'Per DM CLR: Please review response to this field if this should be 'YES' as the indication specified that this is a supplement. Please update accordingly. ' answered with 'updated' (Site from DM).	Shetel Anassi (b) (4) (b) (4)	09 Nov 2020 18:13:03
User entered 'Yes (Y)' reason for change: Data Entry Error	Shetel Anassi (b) (4) (b) (4)	09 Nov 2020 18:12:55
User opened query 'Per DM CLR: Please review response to this field if this should be 'YES' as the indication specified that this is a supplement. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	08 Nov 2020 10:25:40
User entered 'No (N)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:51:37

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 10:07:51
Indication

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'Supplement'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:51:37

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 10:07:51
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered '1'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:51:37

FDA-CBER-2022-1614-3767228

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 10:07:51
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'tablet (TABLET)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:51:37

FDA-CBER-2022-1614-3767229

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 10:07:51
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered empty.	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:51:37

FDA-CBER-2022-1614-3767230

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 10:07:51
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'once daily (QD)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:51:37

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 10:07:51
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered empty.	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:51:37

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 10:07:51
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'Oral (ORAL)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:51:37

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 10:07:51
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered empty.	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:51:37

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 10:07:51
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'un UNK 2016'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:51:37

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 10:07:51
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered '0'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:51:37

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 10:07:51
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'Yes (Y)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:51:37

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 10:07:51
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered empty.	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:51:37

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 10:07:51
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'No (N)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:51:37

FDA-CBER-2022-1614-3767239

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 10:07:51
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 14:51:37

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 10:07:51
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 14:51:37

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 10:07:51
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Sep 2020 14:51:37

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 10:07:51
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: ALPRAZOLAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Sep 2020 14:54:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Sep 2020 14:54:47
Data point term sent to Coder	System	14 Sep 2020 14:53:28
User entered 'alprazolam'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:52:58

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 10:07:51
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'No (N)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:52:58

FDA-CBER-2022-1614-3767244

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 10:07:51
Indication

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'Insomnia'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:52:58

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 10:07:51
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered '.25'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:52:58

FDA-CBER-2022-1614-3767246

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 10:07:51
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'mg (mg)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:52:58

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 10:07:51
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered empty.	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:52:58

FDA-CBER-2022-1614-3767248

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 10:07:51
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'once daily (QD)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:52:58

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 10:07:51
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered empty.	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:52:58

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 10:07:51
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'Oral (ORAL)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:52:58

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 10:07:51
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered empty.	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:52:58

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 10:07:51
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'un UNK 2008'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:52:58

FDA-CBER-2022-1614-3767253

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 10:07:51
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered '0'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:52:58

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 10:07:51
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'Yes (Y)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:52:58

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 10:07:51
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered empty.	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:52:58

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 10:07:51
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'No (N)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:52:58

FDA-CBER-2022-1614-3767257

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 10:07:51
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 14:52:58

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 10:07:51
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 14:52:58

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 10:07:51
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Sep 2020 14:52:58

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 10:07:51
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Sep 2020 14:55:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Sep 2020 14:55:52
Data point term sent to Coder	System	14 Sep 2020 14:54:29
User entered 'Aspirin'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:53:50

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 10:07:51
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'No (N)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:53:50

FDA-CBER-2022-1614-3767262

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 10:07:51
Indication

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'coronary artery disease'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:53:50

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 10:07:51
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered '81'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:53:50

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 10:07:51
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'mg (mg)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:53:50

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 10:07:51
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered empty.	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:53:50

FDA-CBER-2022-1614-3767266

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 10:07:51
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'once daily (QD)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:53:50

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 10:07:51
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered empty.	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:53:50

FDA-CBER-2022-1614-3767268

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 10:07:51
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'Oral (ORAL)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:53:50

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 10:07:51
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered empty.	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:53:50

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 10:07:51
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'un UNK 2005'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:53:50

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 10:07:51
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered '0'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:53:50

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 10:07:51
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'Yes (Y)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:53:50

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 10:07:51
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered empty.	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:53:50

FDA-CBER-2022-1614-3767274

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 10:07:51
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'No (N)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:53:50

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 10:07:51
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 14:53:50

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 10:07:51
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 14:53:50

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 10:07:51
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Sep 2020 14:53:50

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 10:07:51
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIGOUT PREPARATIONS, ATC: ANTIGOUT PREPARATIONS, ATC: PREPARATIONS INHIBITING URIC ACID PRODUCTION, PRODUCT: ALLOPURINOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Sep 2020 14:55:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Sep 2020 14:55:52
Data point term sent to Coder	System	14 Sep 2020 14:55:30
User entered 'allopurinol'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:54:44

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 10:07:51
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'No (N)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:54:44

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 10:07:51
Indication

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:26:25
Query 'Per DM CLR: Please update the indication to reflect the location of Gout. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:03:20
User opened query 'Per DM CLR: Please update the indication to reflect the location of Gout. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Nov 2020 10:24:49
User entered 'gout'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:54:44

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 10:07:51
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered '100'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:54:44

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 10:07:51
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'mg (mg)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:54:44

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 10:07:51
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered empty.	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:54:44

FDA-CBER-2022-1614-3767284

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 10:07:51
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'once daily (QD)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:54:44

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 10:07:51
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered empty.	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:54:44

FDA-CBER-2022-1614-3767286

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 10:07:51
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'Oral (ORAL)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:54:44

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 10:07:51
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered empty.	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:54:44

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 10:07:51
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'un UNK 2016'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:54:44

FDA-CBER-2022-1614-3767289

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 10:07:51
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered '0'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:54:44

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 10:07:51
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'Yes (Y)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:54:44

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 10:07:51
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered empty.	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:54:44

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 10:07:51
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'No (N)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:54:44

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 10:07:51
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 14:54:44

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 10:07:51
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 14:54:44

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 10:07:51
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Sep 2020 14:54:44

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 10:07:51
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Sep 2020 14:57:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Sep 2020 14:57:51
Data point term sent to Coder	System	14 Sep 2020 14:56:34
User entered 'Vitamin D3'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:56:16

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 10:07:51
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:26:25
User closed query 'Per DM CLR: Please review response to this field if this should be 'YES' as the indication specified that this is a supplement. Please update accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Nov 2020 13:37:50
Query 'Per DM CLR: Please review response to this field if this should be 'YES' as the indication specified that this is a supplement. Please update accordingly. ' answered with 'Updated' (Site from DM).	Shetel Anassi (b) (4) (b) (4)	09 Nov 2020 20:55:39
User entered 'Yes (Y)' reason for change: Data Entry Error	Shetel Anassi (b) (4) (b) (4)	09 Nov 2020 20:55:34
User opened query 'Per DM CLR: Please review response to this field if this should be 'YES' as the indication specified that this is a supplement. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	08 Nov 2020 10:26:18
User entered 'No (N)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:56:16

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 10:07:51
Indication

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'supplement'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:56:16

FDA-CBER-2022-1614-3767299

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 10:07:51
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered '2000'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:56:16

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 10:07:51
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'IU (IU)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:56:16

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 10:07:51
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered empty.	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:56:16

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 10:07:51
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'once daily (QD)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:56:16

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 10:07:51
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered empty.	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:56:16

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 10:07:51
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'Oral (ORAL)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:56:16

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 10:07:51
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered empty.	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:56:16

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 10:07:51
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'un UNK 2016'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:56:16

FDA-CBER-2022-1614-3767307

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 10:07:51
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered '0'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:56:16

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 10:07:51
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'Yes (Y)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:56:16

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 10:07:51
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered empty.	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:56:16

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 10:07:51
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'No (N)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:56:16

FDA-CBER-2022-1614-3767311

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 10:07:51
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 14:56:16

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 10:07:51
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 14:56:16

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 10:07:51
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Sep 2020 14:56:16

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 10:07:51
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Sep 2020 14:59:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Sep 2020 14:59:46
Data point term sent to Coder	System	14 Sep 2020 14:58:37
User entered 'pantoprazole'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:57:42

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 10:07:51
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'No (N)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:57:42

FDA-CBER-2022-1614-3767316

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 10:07:51
Indication

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'Peptic Ulcer'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:57:42

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 10:07:51
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered '40'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:57:42

FDA-CBER-2022-1614-3767318

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 10:07:51
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'mg (mg)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:57:42

FDA-CBER-2022-1614-3767319

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 10:07:51
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered empty.	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:57:42

FDA-CBER-2022-1614-3767320

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 10:07:51
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'once daily (QD)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:57:42

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 10:07:51
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered empty.	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:57:42

FDA-CBER-2022-1614-3767322

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 10:07:51
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'Oral (ORAL)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:57:42

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 10:07:51
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered empty.	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:57:42

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 10:07:51
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'un UNK 2016'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:57:42

FDA-CBER-2022-1614-3767325

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 10:07:51
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered '0'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:57:42

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 10:07:51
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'Yes (Y)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:57:42

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 10:07:51
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered empty.	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:57:42

FDA-CBER-2022-1614-3767328

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 10:07:51
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'No (N)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 14:57:42

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 10:07:51
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 14:57:42

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 10:07:51
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 14:57:42

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 10:07:51
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Sep 2020 14:57:42

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 10:07:51
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: ANTIARRHYTHMICS, CLASS I AND III, ATC: ANTIARRHYTHMICS, CLASS III, PRODUCT: AMIODARONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Sep 2020 15:03:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Sep 2020 15:03:51
Data point term sent to Coder	System	14 Sep 2020 15:02:52
User entered 'amiodarone'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 15:02:22

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 10:07:51
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'No (N)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 15:02:22

FDA-CBER-2022-1614-3767334

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 10:07:51
Indication

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'Atrial fibrillation'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 15:02:22

FDA-CBER-2022-1614-3767335

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 10:07:51
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered '200'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 15:02:22

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 10:07:51
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'mg (mg)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 15:02:22

FDA-CBER-2022-1614-3767337

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 10:07:51
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered empty.	Trent Davis (b) (4) (b) (4)	14 Sep 2020 15:02:22

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 10:07:51
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'once daily (QD)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 15:02:22

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 10:07:51
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered empty.	Trent Davis (b) (4) (b) (4)	14 Sep 2020 15:02:22

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 10:07:51
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'Oral (ORAL)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 15:02:22

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 10:07:51
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered empty.	Trent Davis (b) (4) (b) (4)	14 Sep 2020 15:02:22

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 10:07:51
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'un Jan 2020'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 15:02:22

FDA-CBER-2022-1614-3767343

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 10:07:51
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered '0'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 15:02:22

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 10:07:51
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'Yes (Y)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 15:02:22

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 10:07:51
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered empty.	Trent Davis (b) (4) (b) (4)	14 Sep 2020 15:02:22

FDA-CBER-2022-1614-3767346

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 10:07:51
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'No (N)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 15:02:22

FDA-CBER-2022-1614-3767347

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 10:07:51
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 15:02:22

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 10:07:51
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 15:02:22

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 10:07:51
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Sep 2020 15:02:22

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 10:07:51
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:21
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
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)	14 Sep 2020 15:04:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Sep 2020 15:04:49
Data point term sent to Coder	System	14 Sep 2020 15:03:55
User entered 'Eliquis'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 15:03:09

FDA-CBER-2022-1614-3767351

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 10:07:51
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:21
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'No (N)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 15:03:09

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 10:07:51
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:21
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'Atrial fibrillation'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 15:03:09

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 10:07:51
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:21
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered '5'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 15:03:09

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 10:07:51
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:21
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'mg (mg)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 15:03:09

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 10:07:51
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:21
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered empty.	Trent Davis (b) (4) (b) (4)	14 Sep 2020 15:03:09

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 10:07:51
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:21
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'once daily (QD)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 15:03:09

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 10:07:51
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:21
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered empty.	Trent Davis (b) (4) (b) (4)	14 Sep 2020 15:03:09

FDA-CBER-2022-1614-3767358

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 10:07:51
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:21
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'Oral (ORAL)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 15:03:09

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 10:07:51
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:21
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered empty.	Trent Davis (b) (4) (b) (4)	14 Sep 2020 15:03:09

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 10:07:51
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:21
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'un Jan 2020'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 15:03:09

FDA-CBER-2022-1614-3767361

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 10:07:51
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:21
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered '0'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 15:03:09

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 10:07:51
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:21
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	08 Mar 2021 16:34:57
User entered 'Yes (Y)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 15:03:09

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 10:07:51
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:21
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:26:25
User entered '15 Jan 2021' reason for change: New Information	(b) (4) (b) (4), (b) (6)	08 Mar 2021 16:34:57
User entered empty.	Trent Davis (b) (4) (b) (4)	14 Sep 2020 15:03:09

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 10:07:51
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:21
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'No (N)'	Trent Davis (b) (4) (b) (4)	14 Sep 2020 15:03:09

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 10:07:51
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:21
User entered '1'	System	14 Sep 2020 15:03:09

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 10:07:51
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:21
User entered '1'	System	14 Sep 2020 15:03:09

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 10:07:51
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:21
User entered '804 (804)'	System	14 Sep 2020 15:03:09

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 10:07:51
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:24
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 21:03:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 21:03:31
Data point term sent to Coder	System	03 Nov 2020 21:02:18
User entered 'Tylenol'	Trent Davis (b) (4) (b) (4)	03 Nov 2020 21:01:59

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 10:07:51
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:24
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'No (N)'	Trent Davis (b) (4) (b) (4)	03 Nov 2020 21:01:59

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 10:07:51
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:26:25
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the INJECTION SITE PAIN is considered a solicited local or systemic adverse reaction and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION SITE PAIN did not meet the AE reporting criteria. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 12:06:09
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the INJECTION SITE PAIN is considered a solicited local or systemic adverse reaction and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION SITE PAIN did not meet the AE reporting criteria. ' answered with 'This is a solicited adverse reaction and does not meet AE reporting criteria. ' (Site from DM).	Sandra Francisco (b) (4) (b) (4)	09 Mar 2021 16:55:19

FDA-CBER-2022-1614-3767371

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 10:07:51
Indication

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the INJECTION SITE PAIN is considered a solicited local or systemic adverse reaction and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION SITE PAIN did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 14:41:40
User entered 'injection site pain'	Trent Davis (b) (4) (b) (4)	03 Nov 2020 21:01:59

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 10:07:51
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:24
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered '500'	Trent Davis (b) (4) (b) (4)	03 Nov 2020 21:01:59

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 10:07:51
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:24
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'mg (mg)'	Trent Davis (b) (4) (b) (4)	03 Nov 2020 21:01:59

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 10:07:51
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:24
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered empty.	Trent Davis (b) (4) (b) (4)	03 Nov 2020 21:01:59

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 10:07:51
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:24
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'once daily (QD)'	Trent Davis (b) (4) (b) (4)	03 Nov 2020 21:01:59

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 10:07:51
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:24
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered empty.	Trent Davis (b) (4) (b) (4)	03 Nov 2020 21:01:59

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 10:07:51
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:24
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'Oral (ORAL)'	Trent Davis (b) (4) (b) (4)	03 Nov 2020 21:01:59

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 10:07:51
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:24
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered empty.	Trent Davis (b) (4) (b) (4)	03 Nov 2020 21:01:59

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 10:07:51
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:24
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered '08 Oct 2020'	Trent Davis (b) (4) (b) (4)	03 Nov 2020 21:01:59

FDA-CBER-2022-1614-3767380

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 10:07:51
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:24
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered '0'	Trent Davis (b) (4) (b) (4)	03 Nov 2020 21:01:59

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 10:07:51
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:24
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'No (N)'	Trent Davis (b) (4) (b) (4)	03 Nov 2020 21:01:59

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 10:07:51
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:24
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered '08 Oct 2020'	Trent Davis (b) (4) (b) (4)	03 Nov 2020 21:01:59

FDA-CBER-2022-1614-3767383

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 10:07:51
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:24
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'Yes (Y)'	Trent Davis (b) (4) (b) (4)	03 Nov 2020 21:01:59

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 10:07:51
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:24
User entered '1'	System	03 Nov 2020 21:01:59

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 10:07:51
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:24
User entered '1'	System	03 Nov 2020 21:01:59

FDA-CBER-2022-1614-3767386

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 10:07:51
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:24
User entered '804 (804)'	System	03 Nov 2020 21:01:59

FDA-CBER-2022-1614-3767387

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 10:07:51
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:28
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE INACT SPLIT 3V, PRODUCTSYNONYM: FLUZONE HIGH DOSE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 05:16:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 05:16:39
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
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)	04 Nov 2020 05:03:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 05:03:18
Data point term sent to Coder	System	03 Nov 2020 21:04:22
User entered 'Fluzone high dose flu vaccine'	Trent Davis (b) (4) (b) (4)	03 Nov 2020 21:04:19

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 10:07:51
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:28
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'Yes (Y)'	Trent Davis (b) (4) (b) (4)	03 Nov 2020 21:04:19

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 10:07:51
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:28
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'Prophylaxis for influenza'	Trent Davis (b) (4) (b) (4)	03 Nov 2020 21:04:19

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 10:07:51
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:28
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered '.5'	Trent Davis (b) (4) (b) (4)	03 Nov 2020 21:04:19

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 10:07:51
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:28
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'mL (mL)'	Trent Davis (b) (4) (b) (4)	03 Nov 2020 21:04:19

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 10:07:51
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:28
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered empty.	Trent Davis (b) (4) (b) (4)	03 Nov 2020 21:04:19

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 10:07:51
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:28
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'once (ONCE)'	Trent Davis (b) (4) (b) (4)	03 Nov 2020 21:04:19

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 10:07:51
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:28
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered empty.	Trent Davis (b) (4) (b) (4)	03 Nov 2020 21:04:19

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 10:07:51
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:28
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'Intramuscular (INTRAMUSCULAR)'	Trent Davis (b) (4) (b) (4)	03 Nov 2020 21:04:19

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 10:07:51
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:28
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered empty.	Trent Davis (b) (4) (b) (4)	03 Nov 2020 21:04:19

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 10:07:51
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:28
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered '14 Aug 2020'	Trent Davis (b) (4) (b) (4)	03 Nov 2020 21:04:19

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 10:07:51
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:28
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered '0'	Trent Davis (b) (4) (b) (4)	03 Nov 2020 21:04:19

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 10:07:51
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:28
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'No (N)'	Trent Davis (b) (4) (b) (4)	03 Nov 2020 21:04:19

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 10:07:51
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:28
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered '14 Aug 2020'	Trent Davis (b) (4) (b) (4)	03 Nov 2020 21:04:19

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 10:07:51
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:28
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'No (N)'	Trent Davis (b) (4) (b) (4)	03 Nov 2020 21:04:19

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 10:07:51
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:28
User entered empty.	System	03 Nov 2020 21:04:19

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 10:07:51
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:28
User entered empty.	System	03 Nov 2020 21:04:19

US3862141
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 10:07:51
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:54:28
User entered empty.	System	03 Nov 2020 21:04:19

US3862141
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures Summary
Generated On: 10 Jun 2021 10:07:51
Were any concomitant procedures performed?

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
User entered 'No (N)'	Chanei Henry (b) (4) (b) (4)	26 Mar 2021 18:25:46

US3862141
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 10 Jun 2021 10:07:51
Date of study discontinuation/completion *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:32:26
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	23 Apr 2021 14:01:28
User entered '09 Mar 2021'	Sandra Francisco (b) (4) (b) (4)	20 Apr 2021 18:13:46

FDA-CBER-2022-1614-3767407

US3862141
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 10 Jun 2021 10:07:51
Reason for discontinuation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:32:26
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	23 Apr 2021 14:01:28
User entered 'Death (DEATH)'	Sandra Francisco (b) (4) (b) (4)	20 Apr 2021 18:13:46

US3862141
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 10 Jun 2021 10:07:51
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)	29 Apr 2021 05:32:26
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	23 Apr 2021 14:01:28
User entered empty.	Sandra Francisco (b) (4) (b) (4)	20 Apr 2021 18:13:46

US3862141
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 10 Jun 2021 10:07:51
If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:32:26
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 14:01:28
User entered 'Adverse event (ADVERSE EVENT)'	Sandra Francisco (b) (4) (b) (4)	20 Apr 2021 18:13:46

US3862141
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 10 Jun 2021 10:07:51
If main cause of death is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:32:26
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	23 Apr 2021 14:01:28
User entered empty.	Sandra Francisco (b) (4) (b) (4)	20 Apr 2021 18:13:46

US3862141
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 10 Jun 2021 10:07:51
Date of death *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:32:26
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	23 Apr 2021 14:01:28
User entered '09 Mar 2021'	Sandra Francisco (b) (4) (b) (4)	20 Apr 2021 18:13:46

US3862141
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 10 Jun 2021 10:07:51
Was autopsy performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:32:26
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	23 Apr 2021 14:01:28
User entered 'Unknown (UNK)'	Sandra Francisco (b) (4) (b) (4)	20 Apr 2021 18:13:46

FDA-CBER-2022-1614-3767413

US3862141
Folder: SAE USA-US121-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:07:51
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:26:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:10:51
Reviewed for Safety.		10 Mar 2021 15:18:18
User entered 'USA-US121-2021-MRNA-1273-P301000004'	System	10 Mar 2021 15:04:46

FDA-CBER-2022-1614-3767414

US3862141
Folder: SAE USA-US121-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:07:51
Serious

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:26:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:10:51
Reviewed for Safety.		10 Mar 2021 15:20:25
User entered 'Yes (Y)'	System	10 Mar 2021 15:04:46

US3862141
Folder: SAE USA-US121-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:07:51
Death

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:26:25
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 17:27:48
DataPoint Verified.		18 Mar 2021 17:10:51
Un-reviewed for Safety.	System	17 Mar 2021 16:33:19
User entered 'Yes (Y)'	System	17 Mar 2021 16:33:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 15:20:25
User entered 'No (N)'	System	10 Mar 2021 15:04:46

US3862141
Folder: SAE USA-US121-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:07:51
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:26:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:10:51
Reviewed for Safety.		10 Mar 2021 15:20:25
User entered 'Yes (Y)'	System	10 Mar 2021 15:04:46

FDA-CBER-2022-1614-3767417

US3862141
Folder: SAE USA-US121-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:07:51
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:26:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:10:51
Reviewed for Safety.		10 Mar 2021 15:20:25
User entered 'Yes (Y)'	System	10 Mar 2021 15:04:46

US3862141
Folder: SAE USA-US121-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:07:51
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:26:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:10:51
Reviewed for Safety.		10 Mar 2021 15:20:25
User entered 'No (N)'	System	10 Mar 2021 15:04:46

US3862141
Folder: SAE USA-US121-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:07:51
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:26:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:10:51
Reviewed for Safety.		10 Mar 2021 15:20:25
User entered 'No (N)'	System	10 Mar 2021 15:04:46

FDA-CBER-2022-1614-3767420

US3862141
Folder: SAE USA-US121-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:07:51
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:26:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:10:51
Reviewed for Safety.		10 Mar 2021 15:20:25
User entered 'No (N)'	System	10 Mar 2021 15:04:46

US3862141
Folder: SAE USA-US121-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:07:51
Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:26:25
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 17:27:48
DataPoint Verified.		18 Mar 2021 17:10:51
Un-reviewed for Safety.	System	17 Mar 2021 16:33:19
User entered 'Thea Marie'	System	17 Mar 2021 16:33:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 15:20:25
User entered 'Hana'	System	10 Mar 2021 15:04:46

US3862141
Folder: SAE USA-US121-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:07:51
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:26:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 17:27:48
DataPoint Verified.		18 Mar 2021 17:10:51
Un-reviewed for Safety.	System	17 Mar 2021 16:33:19
User entered 'Cordero'	System	17 Mar 2021 16:33:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 15:20:25
User entered 'El Sahly'	System	10 Mar 2021 15:04:46

US3862141
Folder: SAE USA-US121-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:07:51
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:26:25
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 17:27:48
DataPoint Verified.		18 Mar 2021 17:10:51
Un-reviewed for Safety.	System	17 Mar 2021 16:33:19
User entered 'One Baylor Plaza, MS 280, Room 221D'	System	17 Mar 2021 16:33:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 15:20:25
User entered 'One Baylor Plaza'	System	10 Mar 2021 15:04:46

US3862141
Folder: SAE USA-US121-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:07:51
Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:26:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:10:51
Reviewed for Safety.		10 Mar 2021 15:20:25
User entered 'Houston'	System	10 Mar 2021 15:04:46

US3862141
Folder: SAE USA-US121-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:07:51
Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:26:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:10:51
Reviewed for Safety.		10 Mar 2021 15:20:25
User entered 'TX'	System	10 Mar 2021 15:04:46

FDA-CBER-2022-1614-3767426

US3862141
Folder: SAE USA-US121-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:07:51
Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:26:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:10:51
Reviewed for Safety.		10 Mar 2021 15:20:25
User entered '77030'	System	10 Mar 2021 15:04:46

FDA-CBER-2022-1614-3767427

US3862141
Folder: SAE USA-US121-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:07:51
Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:26:25
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:10:51
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 15:20:25
User entered 'US'	System	10 Mar 2021 15:12:00

US3862141
Folder: SAE USA-US121-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:07:51
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '3'	System	22 Mar 2021 17:27:57
User entered '2'	System	18 Mar 2021 14:32:36
User entered '1'	System	10 Mar 2021 15:12:00

US3862141
Folder: SAE USA-US121-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:07:51
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:26:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:10:51
Reviewed for Safety.		10 Mar 2021 15:18:18
User entered 'USA-US121-2021-MRNA-1273-P301000004'	System	10 Mar 2021 15:04:46

US3862141
Folder: SAE USA-US121-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:07:51
Serious

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:26:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:10:51
Reviewed for Safety.		10 Mar 2021 15:20:25
User entered 'Yes (Y)'	System	10 Mar 2021 15:04:46

US3862141
Folder: SAE USA-US121-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:07:51
Death

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:26:25
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 17:27:48
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:10:51
Un-reviewed for Safety.	System	17 Mar 2021 16:33:19
User entered 'Yes (Y)'	System	17 Mar 2021 16:33:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 15:20:25
User entered 'No (N)'	System	10 Mar 2021 15:04:46

US3862141
Folder: SAE USA-US121-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:07:51
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:26:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:10:51
Reviewed for Safety.		10 Mar 2021 15:20:25
User entered 'Yes (Y)'	System	10 Mar 2021 15:04:46

US3862141
Folder: SAE USA-US121-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:07:51
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:26:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:10:51
Reviewed for Safety.		10 Mar 2021 15:20:25
User entered 'Yes (Y)'	System	10 Mar 2021 15:04:46

US3862141
Folder: SAE USA-US121-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:07:51
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:26:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:10:51
Reviewed for Safety.		10 Mar 2021 15:20:25
User entered 'No (N)'	System	10 Mar 2021 15:04:46

US3862141
Folder: SAE USA-US121-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:07:51
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:26:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:10:51
Reviewed for Safety.		10 Mar 2021 15:20:25
User entered 'No (N)'	System	10 Mar 2021 15:04:46

US3862141
Folder: SAE USA-US121-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:07:51
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:26:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:10:51
Reviewed for Safety.		10 Mar 2021 15:20:25
User entered 'No (N)'	System	10 Mar 2021 15:04:46

US3862141
Folder: SAE USA-US121-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:07:51
Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:26:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 17:27:48
DataPoint Verified.		18 Mar 2021 17:10:51
Un-reviewed for Safety.	System	17 Mar 2021 16:33:19
User entered 'Thea Marie'	System	17 Mar 2021 16:33:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 15:20:25
User entered 'Hana'	System	10 Mar 2021 15:04:46

US3862141
Folder: SAE USA-US121-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:07:51
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:26:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 17:27:48
DataPoint Verified.		18 Mar 2021 17:10:51
Un-reviewed for Safety.	System	17 Mar 2021 16:33:19
User entered 'Cordero'	System	17 Mar 2021 16:33:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 15:20:25
User entered 'El Sahly'	System	10 Mar 2021 15:04:46

US3862141
Folder: SAE USA-US121-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:07:51
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:26:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 17:27:48
DataPoint Verified.		18 Mar 2021 17:10:51
Un-reviewed for Safety.	System	17 Mar 2021 16:33:19
User entered 'One Baylor Plaza, MS 280, Room 221D'	System	17 Mar 2021 16:33:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 15:20:25
User entered 'One Baylor Plaza'	System	10 Mar 2021 15:04:46

US3862141
Folder: SAE USA-US121-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:07:51
Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:26:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:10:51
Reviewed for Safety.		10 Mar 2021 15:20:25
User entered 'Houston'	System	10 Mar 2021 15:04:46

FDA-CBER-2022-1614-3767441

US3862141
Folder: SAE USA-US121-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:07:51
Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:26:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:10:51
Reviewed for Safety.		10 Mar 2021 15:20:25
User entered 'TX'	System	10 Mar 2021 15:04:46

FDA-CBER-2022-1614-3767442

US3862141
Folder: SAE USA-US121-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:07:51
Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:26:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:10:51
Reviewed for Safety.		10 Mar 2021 15:20:25
User entered '77030'	System	10 Mar 2021 15:04:46

FDA-CBER-2022-1614-3767443

US3862141
Folder: SAE USA-US121-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:07:51
Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:26:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:10:51
Reviewed for Safety.		10 Mar 2021 15:20:25
User entered 'US'	System	10 Mar 2021 15:12:00

US3862141
Folder: SAE USA-US121-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:07:51
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '3'	System	22 Mar 2021 17:27:57
User entered '2'	System	18 Mar 2021 14:32:36
User entered '1'	System	10 Mar 2021 15:12:00

US3862141
Folder: SAE USA-US121-2021-MRNA-1273-P301000004
Form: Safety Report Form (1)
Generated On: 10 Jun 2021 10:07:51
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:26:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:10:51
User entered '10/Mar/2021 10:11'	System	10 Mar 2021 15:12:00

FDA-CBER-2022-1614-3767446

US3862141

Folder: SAE USA-US121-2021-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 10:07:51

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:10:51
Reviewed for Safety.		10 Mar 2021 15:20:25
User entered '1'		10 Mar 2021 15:12:00

US3862141
Folder: SAE USA-US121-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:07:51
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:26:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:10:51
Reviewed for Safety.		10 Mar 2021 15:18:18
User entered 'USA-US121-2021-MRNA-1273-P301000004'	System	10 Mar 2021 15:04:46

FDA-CBER-2022-1614-3767448

US3862141
Folder: SAE USA-US121-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:07:51
Serious

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:26:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:10:51
Reviewed for Safety.		10 Mar 2021 15:20:25
User entered 'Yes (Y)'	System	10 Mar 2021 15:04:46

US3862141
Folder: SAE USA-US121-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:07:51
Death

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:26:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 17:27:48
DataPoint Verified.		18 Mar 2021 17:10:51
Un-reviewed for Safety.	System	17 Mar 2021 16:33:19
User entered 'Yes (Y)'	System	17 Mar 2021 16:33:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 15:20:25
User entered 'No (N)'	System	10 Mar 2021 15:04:46

US3862141
Folder: SAE USA-US121-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:07:51
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:26:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:10:51
Reviewed for Safety.		10 Mar 2021 15:20:25
User entered 'Yes (Y)'	System	10 Mar 2021 15:04:46

US3862141
Folder: SAE USA-US121-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:07:51
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:26:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:10:51
Reviewed for Safety.		10 Mar 2021 15:20:25
User entered 'Yes (Y)'	System	10 Mar 2021 15:04:46

US3862141
Folder: SAE USA-US121-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:07:51
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:26:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:10:51
Reviewed for Safety.		10 Mar 2021 15:20:25
User entered 'No (N)'	System	10 Mar 2021 15:04:46

US3862141
Folder: SAE USA-US121-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:07:51
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:26:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:10:51
Reviewed for Safety.		10 Mar 2021 15:20:25
User entered 'No (N)'	System	10 Mar 2021 15:04:46

US3862141
Folder: SAE USA-US121-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:07:51
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:26:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:10:51
Reviewed for Safety.		10 Mar 2021 15:20:25
User entered 'No (N)'	System	10 Mar 2021 15:04:46

US3862141
Folder: SAE USA-US121-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:07:51
Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:26:25
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 17:27:48
DataPoint Verified.		18 Mar 2021 17:10:51
Un-reviewed for Safety.	System	17 Mar 2021 16:33:19
User entered 'Thea Marie'	System	17 Mar 2021 16:33:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 15:20:25
User entered 'Hana'	System	10 Mar 2021 15:04:46

US3862141
Folder: SAE USA-US121-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:07:51
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:26:25
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 17:27:48
DataPoint Verified.		18 Mar 2021 17:10:51
Un-reviewed for Safety.	System	17 Mar 2021 16:33:19
User entered 'Cordero'	System	17 Mar 2021 16:33:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 15:20:25
User entered 'El Sahly'	System	10 Mar 2021 15:04:46

US3862141
Folder: SAE USA-US121-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:07:51
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:26:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 17:27:48
DataPoint Verified.		18 Mar 2021 17:10:51
Un-reviewed for Safety.	System	17 Mar 2021 16:33:19
User entered 'One Baylor Plaza, MS 280, Room 221D'	System	17 Mar 2021 16:33:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 15:20:25
User entered 'One Baylor Plaza'	System	10 Mar 2021 15:04:46

US3862141
Folder: SAE USA-US121-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:07:51
Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:26:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:10:51
Reviewed for Safety.		10 Mar 2021 15:20:25
User entered 'Houston'	System	10 Mar 2021 15:04:46

US3862141
Folder: SAE USA-US121-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:07:51
Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:26:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:10:51
Reviewed for Safety.		10 Mar 2021 15:20:25
User entered 'TX'	System	10 Mar 2021 15:04:46

US3862141
Folder: SAE USA-US121-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:07:51
Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:26:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:10:51
Reviewed for Safety.		10 Mar 2021 15:20:25
User entered '77030'	System	10 Mar 2021 15:04:46

FDA-CBER-2022-1614-3767461

US3862141
Folder: SAE USA-US121-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:07:51
Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:26:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:10:51
Reviewed for Safety.		10 Mar 2021 15:20:25
User entered 'US'	System	10 Mar 2021 15:12:00

US3862141
Folder: SAE USA-US121-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:07:51
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '3'	System	22 Mar 2021 17:27:57
User entered '2'	System	18 Mar 2021 14:32:36
User entered '1'	System	10 Mar 2021 15:12:00

US3862141
Folder: SAE USA-US121-2021-MRNA-1273-P301000004
Form: Safety Report Form (2)
Generated On: 10 Jun 2021 10:07:51
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:26:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:10:51
User entered '18/Mar/2021 07:32'	System	18 Mar 2021 14:32:36

FDA-CBER-2022-1614-3767464

US3862141

Folder: SAE USA-US121-2021-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 10:07:51

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:26:25
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 17:27:48
DataPoint Verified.		18 Mar 2021 17:10:51
User entered '1'		18 Mar 2021 14:32:36

US3862141
Folder: SAE USA-US121-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:07:51
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:26:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:10:51
Reviewed for Safety.		10 Mar 2021 15:18:18
User entered 'USA-US121-2021-MRNA-1273-P301000004'	System	10 Mar 2021 15:04:46

US3862141
Folder: SAE USA-US121-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:07:51
Serious

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:26:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:10:51
Reviewed for Safety.		10 Mar 2021 15:20:25
User entered 'Yes (Y)'	System	10 Mar 2021 15:04:46

US3862141
Folder: SAE USA-US121-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:07:51
Death

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:26:25
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 17:27:48
DataPoint Verified.		18 Mar 2021 17:10:51
Un-reviewed for Safety.	System	17 Mar 2021 16:33:19
User entered 'Yes (Y)'	System	17 Mar 2021 16:33:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 15:20:25
User entered 'No (N)'	System	10 Mar 2021 15:04:46

US3862141
Folder: SAE USA-US121-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:07:51
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:26:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:10:51
Reviewed for Safety.		10 Mar 2021 15:20:25
User entered 'Yes (Y)'	System	10 Mar 2021 15:04:46

FDA-CBER-2022-1614-3767469

US3862141
Folder: SAE USA-US121-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:07:51
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:26:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:10:51
Reviewed for Safety.		10 Mar 2021 15:20:25
User entered 'Yes (Y)'	System	10 Mar 2021 15:04:46

US3862141
Folder: SAE USA-US121-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:07:51
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:26:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:10:51
Reviewed for Safety.		10 Mar 2021 15:20:25
User entered 'No (N)'	System	10 Mar 2021 15:04:46

US3862141
Folder: SAE USA-US121-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:07:51
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:26:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:10:51
Reviewed for Safety.		10 Mar 2021 15:20:25
User entered 'No (N)'	System	10 Mar 2021 15:04:46

US3862141
Folder: SAE USA-US121-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:07:51
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:26:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:10:51
Reviewed for Safety.		10 Mar 2021 15:20:25
User entered 'No (N)'	System	10 Mar 2021 15:04:46

US3862141
Folder: SAE USA-US121-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:07:51
Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:26:25
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 17:27:48
DataPoint Verified.		18 Mar 2021 17:10:51
Un-reviewed for Safety.	System	17 Mar 2021 16:33:19
User entered 'Thea Marie'	System	17 Mar 2021 16:33:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 15:20:25
User entered 'Hana'	System	10 Mar 2021 15:04:46

US3862141
Folder: SAE USA-US121-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:07:51
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:26:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 17:27:48
DataPoint Verified.		18 Mar 2021 17:10:51
Un-reviewed for Safety.	System	17 Mar 2021 16:33:19
User entered 'Cordero'	System	17 Mar 2021 16:33:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 15:20:25
User entered 'El Sahly'	System	10 Mar 2021 15:04:46

US3862141
Folder: SAE USA-US121-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:07:51
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:26:25
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 17:27:48
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:10:51
Un-reviewed for Safety.	System	17 Mar 2021 16:33:19
User entered 'One Baylor Plaza, MS 280, Room 221D'	System	17 Mar 2021 16:33:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 15:20:25
User entered 'One Baylor Plaza'	System	10 Mar 2021 15:04:46

US3862141
Folder: SAE USA-US121-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:07:51
Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:26:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:10:51
Reviewed for Safety.		10 Mar 2021 15:20:25
User entered 'Houston'	System	10 Mar 2021 15:04:46

FDA-CBER-2022-1614-3767477

US3862141
Folder: SAE USA-US121-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:07:51
Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:26:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:10:51
Reviewed for Safety.		10 Mar 2021 15:20:25
User entered 'TX'	System	10 Mar 2021 15:04:46

US3862141
Folder: SAE USA-US121-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:07:51
Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:26:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:10:51
Reviewed for Safety.		10 Mar 2021 15:20:25
User entered '77030'	System	10 Mar 2021 15:04:46

FDA-CBER-2022-1614-3767479

US3862141
Folder: SAE USA-US121-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:07:51
Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:26:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:10:51
Reviewed for Safety.		10 Mar 2021 15:20:25
User entered 'US'	System	10 Mar 2021 15:12:00

US3862141
Folder: SAE USA-US121-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 10:07:51
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '3'	System	22 Mar 2021 17:27:57
User entered '2'	System	18 Mar 2021 14:32:36
User entered '1'	System	10 Mar 2021 15:12:00

US3862141
Folder: SAE USA-US121-2021-MRNA-1273-P301000004
Form: Safety Report Form (3)
Generated On: 10 Jun 2021 10:07:51
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:04:23
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:26:25
User entered '22/Mar/2021 13:27'	(b) (4) System	22 Mar 2021 17:27:57

FDA-CBER-2022-1614-3767482

US3862141
Folder: SAE USA-US121-2021-MRNA-1273-P301000004
Form: Safety Report Form (3)
Generated On: 10 Jun 2021 10:07:51
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:04:23
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:26:25
User entered '1'	(b) (4), (b) (6)	22 Mar 2021 17:27:57

FDA-CBER-2022-1614-3767483