US3542053 (Prod: George Washington University)

Generated By: KC Joubran

Generated On: 10 Jun 2021 08:13:30

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US3542053
Form: Participant Creation
Data signed: (b) (4) **27 Aug 2020 15:41:43**
Generated On: 10 Jun 2021 08:13:30

Participant ID	US3542053

mRNA-1273-P301 Completion Guidelines

FDA-CBER-2022-1614-2659540

US3542053
Folder: Screening
Form: Visit Date
Data signed: (b) (4) **27 Aug 2020 15:41:44**
Generated On: 10 Jun 2021 08:13:30

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

FDA-CBER-2022-1614-2659541

US3542053
Folder: Screening
Form: Demographics
Data signed: (b) (4) **27 Aug 2020 15:41:44**
Generated On: 10 Jun 2021 08:13:30

Date of Birth (MMM yyyy)	(b) (6) 1961
Age	59
Age Units	YEARS
Age (Derived)	59
Sex	Female ■ Male ☐
Ethnicity	Hispanic or Latino ■ Not Hispanic or Latino ☐ Not Reported ☐ Unknown ☐
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify	
Unknown	False
Not reported	False

FDA-CBER-2022-1614-2659542

US3542053
Folder: Screening
Form: Enrollment
Data signed: (b) (4) **27 Aug 2020 15:41:44**
Generated On: 10 Jun 2021 08:13:30

Date of Informed Consent *(dd MMM yyyy)*	25 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 ☐ Amendment 2 ☐ Amendment 3 ■ Amendment 4 ☐ Amendment 5 ☐
Was participant enrolled in the study?	Yes ■ No ☐
If No, indicate reason for screen fail	Withdrew Consent ☐ Inclusion/Exclusion ☐ Cohort Full ☐ Other ☐
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes ☐ No ■
If Yes, previous participant number	
Enrollment Trigger	1

FDA-CBER-2022-1614-2659543

US3542053
Folder: Screening
Form: Inclusion/Exclusion Criteria Summary
Data signed: (b) (4) **27 Aug 2020 15:41:44**
Generated On: 10 Jun 2021 08:13:30

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

FDA-CBER-2022-1614-2659544

US3542053
Folder: Screening
Form: Medical History Summary
Data signed: (b) (4) **27 Aug 2020 15:41:44**
Generated On: 10 Jun 2021 08:13:30

Were any significant conditions reported?	Yes ■ No ☐

FDA-CBER-2022-1614-2659545

US3542053
Folder: Screening
Form: Medical History (1)
Data signed: (b) (4) **09 Mar 2021 04:08:47**
Generated On: 10 Jun 2021 08:13:30

Condition	MITRAL VALVE REPLACEMENT
Start date (dd MMM yyyy)	UN UNK 1984
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ■
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1984
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1984
Start Year (derived)	1984
Stop Month and Year (derived)	JAN 1984
Stop Year (derived)	1984

FDA-CBER-2022-1614-2659546

US3542053
Folder: Screening
Form: Medical History (2)
Data signed: (b) (4) **09 Mar 2021 04:08:47**
Generated On: 10 Jun 2021 08:13:30

Condition	RHEUMATIC FEVER
Start date (dd MMM yyyy)	UN UNK 1970
Start date completely unknown	False
Condition ongoing at study entry	Yes ■ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1970
Start Year (derived)	1970
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-2659547

US3542053
Folder: Screening
Form: Medical History (3)
Data signed: (b) (4) **09 Mar 2021 04:08:47**
Generated On: 10 Jun 2021 08:13:30

Condition	GASTRITIS
Start date (dd MMM yyyy)	UN JAN 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes ■ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-2659548

US3542053
Folder: Screening
Form: Medical History (4)
Data signed: (b) (4) **09 Mar 2021 04:08:47**
Generated On: 10 Jun 2021 08:13:30

Condition	MENOPAUSE
Start date (dd MMM yyyy)	UN UNK 2013
Start date completely unknown	False
Condition ongoing at study entry	Yes ■ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2013
Start Year (derived)	2013
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-2659549

US3542053
Folder: Screening
Form: Medical History (5)
Data signed: (b) (4) **09 Mar 2021 04:08:47**
Generated On: 10 Jun 2021 08:13:30

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

FDA-CBER-2022-1614-2659550

US3542053
Folder: Screening
Form: Medical History (6)
Data signed: (b) (4) **09 Mar 2021 04:08:47**
Generated On: 10 Jun 2021 08:13:30

Condition	TRANSIENT ISCHEMIC ATTACK
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes ☐ No ■
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	True
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-2659551

US3542053
Folder: Screening
Form: Vital Signs
Data signed: (b) (4) **27 Aug 2020 15:41:44**
Generated On: 10 Jun 2021 08:13:30

Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	25 AUG 2020
Time of assessment *(00:00-23:59)*	09:48 (24 HR)
Vital Signs Date and Time (derived)	25 AUG 2020 09:48
Height *(xxx.x)*	58.5 in
Weight *(xxx.x)*	120 lb
BMI *(xxx.x)*	24.70469 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)	

US3542053
Folder: Screening
Form: Physical Examination
Data signed: (b) (4) **18 Dec 2020 16:14:51**
Generated On: 10 Jun 2021 08:13:30

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

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

FDA-CBER-2022-1614-2659553

US3542053
Folder: Screening
Form: Childbearing Potential
Data signed: (b) (4) **27 Aug 2020 15:41:44**
Generated On: 10 Jun 2021 08:13:30

Date of assessment *(dd MMM yyyy)*	25 AUG 2020
Is the participant of childbearing potential?	Yes ☐ No ■
If No, what is the reason?	Surgically sterile ☐ Post-menopausal ■ Partner medically sterile ☐ Not reached age of Menarche ☐ Other ☐
If Partner medically sterile or Other, specify	
If Surgically sterile, date of surgery *(dd MMM yyyy)*	
Date of surgery unknown	False
If Post-menopausal, date of last menstruation *(dd MMM yyyy)*	UN UNK 2013
Date of last menstruation unknown	False

FDA-CBER-2022-1614-2659554

US3542053
Folder: Screening
Form: Risk of Exposure
Data signed: (b) (4) **27 Aug 2020 15:41:44**
Generated On: 10 Jun 2021 08:13:30

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-2022-1614-2659555

US3542053
Folder: Screening
Form: Risk of Exposure
Data signed: (b) (4) **27 Aug 2020 15:41:44**
Generated On: 10 Jun 2021 08:13:30

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

FDA-CBER-2022-1614-2659556

US3542053
Folder: Visit 1 Day 1
Form: Visit Date
Data signed: (b) (4) **27 Aug 2020 15:41:44**
Generated On: 10 Jun 2021 08:13:30

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	25 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	VISIT1

FDA-CBER-2022-1614-2659557

US3542053
Folder: Visit 1 Day 1
Form: Randomization
Data signed: (b) (4) **08 Oct 2020 02:55:32**
Generated On: 10 Jun 2021 08:13:30

What was the date of randomization? *(dd MMM yyyy)*	25 AUG 2020
What was the participant's randomization number?	108119
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-2022-1614-2659558

US3542053
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Data signed: (b) (4) **27 Aug 2020 15:41:44**
Generated On: 10 Jun 2021 08:13:30

Height	ND - Not Done
Weight	ND - Not Done

FDA-CBER-2022-1614-2659559

US3542053
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Data signed: (b) (4) **27 Aug 2020 15:41:44**
Generated On: 10 Jun 2021 08:13:30

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ■ Post-Dose ☐
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	25 AUG 2020
Time of assessment *(00:00-23:59)*	09:48 (24 HR)
Vital Signs Date and Time (derived)	25 AUG 2020 09:48
Temperature *(xxx.x)*	97.9 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	72 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	79 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-2659560

US3542053
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Data signed: (b) (4) **27 Aug 2020 15:41:44**
Generated On: 10 Jun 2021 08:13:30

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☐ Post-Dose ■
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	25 AUG 2020
Time of assessment *(00:00-23:59)*	11:32 (24 HR)
Vital Signs Date and Time (derived)	25 AUG 2020 11:32
Temperature *(xxx.x)*	98.0 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	65 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	69 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-2659561

US3542053
Folder: Visit 1 Day 1
Form: Physical Examination
Data signed: (b) (4) **18 Dec 2020 16:14:51**
Generated On: 10 Jun 2021 08:13:30

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

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

FDA-CBER-2022-1614-2659562

US3542053
Folder: Visit 1 Day 1
Form: Exposure
Data signed: (b) (4) **27 Aug 2020 15:41:44**
Generated On: 10 Jun 2021 08:13:30

Was study treatment given?	Yes ■ No ☐
If No, reason not given	Participant declined due to Adverse Event ☐ Physician withheld dose due to Adverse Event ☐ Death ☐ Lost To Follow-Up ☐ Physician Decision ☐ Pregnancy ☐ Protocol Deviation ☐ Study Terminated by Sponsor ☐ Withdrawal of Consent by Participant ☐ Confirmed COVID-19 ☐ Other ☐
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment?	MRNA-1273 OR PLACEBO
What was the treatment date? *(dd MMM yyyy)*	25 AUG 2020
What was the treatment time? *(00:00-23:59)*	10:59 (24 HR)
Treatment Date and Time (derived)	25 AUG 2020 10:59
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-2022-1614-2659563

US3542053
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Data signed: (b) (4) **27 Aug 2020 15:41:44**
Generated On: 10 Jun 2021 08:13:30

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	25 AUG 2020
Collection time *(00:00-23:59)*	10:19 (24 HR)
Collection date and time (derived)	25 AUG 2020 10:19

FDA-CBER-2022-1614-2659564

US3542053
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab
Data signed: (b) (4) **27 Aug 2020 15:41:44**
Generated On: 10 Jun 2021 08:13:30

Collection date *(dd MMM yyyy)*			25 AUG 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:20	25 AUG 2020 10:20
Nasopharyngeal Swab 2	No		

FDA-CBER-2022-1614-2659565

US3542053
Folder: Visit 1 Day 1
Form: Continuing
Data signed: (b) (4) **27 Aug 2020 15:41:44**
Generated On: 10 Jun 2021 08:13:30

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

FDA-CBER-2022-1614-2659566

US3542053
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 08:13:30

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.0 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	25 AUG 2020 11:34
PC Open Date & Time	25 AUG 2020 11:19
PC Close Date & Time	25 AUG 2020 13:49

FDA-CBER-2022-1614-2659567

US3542053
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 08:13:30

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**	97.2 °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	25 AUG 2020 22:00
PC Open Date & Time	25 AUG 2020 14:44
PC Close Date & Time	26 AUG 2020 11:59

FDA-CBER-2022-1614-2659568

US3542053
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 08:13:30

TIMEPOINT	DAY 2

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	97.1 °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	26 AUG 2020 21:57
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3542053
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 08:13:30

TIMEPOINT	DAY 3

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	98.0 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	27 AUG 2020 22:05
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3542053
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 08:13:30

TIMEPOINT	DAY 4

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	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	28 AUG 2020 22:32
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3542053
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 08:13:30

TIMEPOINT	DAY 5

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	96.7 °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	30 AUG 2020 00:05
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3542053
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 08:13:30

TIMEPOINT	DAY 6

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	99.4 °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	30 AUG 2020 22:01
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3542053
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 08:13:30

TIMEPOINT	DAY 7

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	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	31 AUG 2020 22:56
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3542053
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 08:13:30

TIMEPOINT	DAY 1, 30 MINUTES AFTER VACCINATION (AT STUDY CLINIC)
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ☑ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ☑
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ☑
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ☑ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	25 AUG 2020 11:34
PC Open Date & Time	25 AUG 2020 11:19
PC Close Date & Time	25 AUG 2020 13:49

FDA-CBER-2022-1614-2659575

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ● Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ●
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ●
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ● Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	25 AUG 2020 22:01
PC Open Date & Time	25 AUG 2020 14:44
PC Close Date & Time	26 AUG 2020 11:59

FDA-CBER-2022-1614-2659576

US3542053
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 08:13:30

TIMEPOINT	DAY 2
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	26 AUG 2020 21:58
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

FDA-CBER-2022-1614-2659577

US3542053
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 08:13:30

TIMEPOINT	DAY 3
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	27 AUG 2020 22:06
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3542053
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 08:13:30

TIMEPOINT	DAY 4
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ● Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ●
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ●
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ● Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	28 AUG 2020 22:33
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

FDA-CBER-2022-1614-2659579

US3542053
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 08:13:30

TIMEPOINT	DAY 5
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	30 AUG 2020 00:06
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

FDA-CBER-2022-1614-2659580

US3542053
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 08:13:30

TIMEPOINT	DAY 6
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	30 AUG 2020 22:02
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

FDA-CBER-2022-1614-2659581

US3542053
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 08:13:30

TIMEPOINT	DAY 7
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	31 AUG 2020 22:56
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

FDA-CBER-2022-1614-2659582

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-2022-1614-2659583

US3542053
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 08:13:30

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	25 AUG 2020 11:35
PC Open Date & Time	25 AUG 2020 11:19
PC Close Date & Time	25 AUG 2020 13:49

FDA-CBER-2022-1614-2659584

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-2022-1614-2659585

US3542053
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 08:13:30

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	25 AUG 2020 22:02
PC Open Date & Time	25 AUG 2020 14:44
PC Close Date & Time	26 AUG 2020 11:59

FDA-CBER-2022-1614-2659586

US3542053
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 08:13:30

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

FDA-CBER-2022-1614-2659587

	Yes ☐
PC Time stamp	26 AUG 2020 21:58
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3542053
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 08:13:30

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

FDA-CBER-2022-1614-2659589

US3542053
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 08:13:30

	Yes ☐
PC Time stamp	27 AUG 2020 22:06
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

FDA-CBER-2022-1614-2659590

US3542053
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 08:13:30

TIMEPOINT	DAY 4
HEADACHE	None ☐
	No interference with activity ☐
	Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity ☐
	Any use of prescription pain reliever or prevents daily activity ☐
FATIGUE	None ☐
	No interference with activity ☐
	Some interference with activity ☐
	Significant; prevents daily activity ☐
MUSCLE ACHES ALL OVER BODY	None ☐
	No interference with activity ☐
	Some interference with activity ☐
	Significant; prevents daily activity ☐
JOINT ACHES IN SEVERAL JOINTS	None ☐
	No interference with activity ☐
	Some interference with activity ☐
	Significant; prevents daily activity ☐
NAUSEA/VOMITING	None ☐
	No interference with activity or 1-2 episodes/24 hours ☐
	Some interference with activity or >2 episodes/24 hours ☐
	Prevents daily activity, requires outpatient IV hydration ☐
CHILLS	None ☐
	No interference with activity ☐
	Some interference with activity not requiring medical attention ☐
	Prevents daily activity and requires medical attention ☐
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ☐

FDA-CBER-2022-1614-2659591

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

US3542053
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 08:13:30

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-2022-1614-2659593

	Yes ☐
PC Time stamp	30 AUG 2020 00:06
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3542053
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 08:13:30

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

FDA-CBER-2022-1614-2659595

US3542053
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 08:13:30

	Yes ☐
PC Time stamp	30 AUG 2020 22:02
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

FDA-CBER-2022-1614-2659596

US3542053
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 08:13:30

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

FDA-CBER-2022-1614-2659597

	Yes ☐
PC Time stamp	31 AUG 2020 22:57
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3542053
Folder: Safety Call Day 8 (1)
Form: Safety Call
Data signed: (b) (4) **05 Sep 2020 15:30:59**
Generated On: 10 Jun 2021 08:13:30

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	2 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-2022-1614-2659599

US3542053
Folder: Safety Call Day 8 (1)
Form: Continuing
Data signed: (b) (4) **05 Sep 2020 15:30:59**
Generated On: 10 Jun 2021 08:13:30

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

FDA-CBER-2022-1614-2659600

US3542053
Folder: Safety Call Day 15 (1)
Form: Safety Call
Data signed: (b) (4) **14 Sep 2020 04:51:57**
Generated On: 10 Jun 2021 08:13:30

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	9 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-2022-1614-2659601

US3542053
Folder: Safety Call Day 15 (1)
Form: Continuing
Data signed: (b) (4) **14 Sep 2020 04:51:57**
Generated On: 10 Jun 2021 08:13:30

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

FDA-CBER-2022-1614-2659602

US3542053
Folder: Safety Call Day 22 (1)
Form: Safety Call
Data signed: (b) (4) **23 Sep 2020 15:17:42**
Generated On: 10 Jun 2021 08:13:30

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

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US3542053
Folder: Safety Call Day 22 (1)
Form: Continuing
Data signed: (b) (4) **23 Sep 2020 15:17:42**
Generated On: 10 Jun 2021 08:13:30

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

FDA-CBER-2022-1614-2659604

US3542053
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Data signed: (b) (4) **23 Sep 2020 15:17:42**
Generated On: 10 Jun 2021 08:13:30

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	21 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	VISIT2

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US3542053
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Data signed: (b) (4) **03 Oct 2020 15:28:20**
Generated On: 10 Jun 2021 08:13:30

Timepoint	Pre-Dose ■ Post-Dose ☐
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	21 SEP 2020
Time of assessment *(00:00-23:59)*	09:03 (24 HR)
Vital Signs Date and Time (derived)	21 SEP 2020 09:03
Temperature *(xxx.x)*	98.1 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	68 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	53 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-2659606

US3542053
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Data signed: (b) (4) **03 Oct 2020 15:28:20**
Generated On: 10 Jun 2021 08:13:30

Timepoint	Pre-Dose ☐ Post-Dose ■
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	21 SEP 2020
Time of assessment *(00:00-23:59)*	10:35 (24 HR)
Vital Signs Date and Time (derived)	21 SEP 2020 10:35
Temperature *(xxx.x)*	98.1 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	63 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	57 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-2659607

US3542053
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Data signed: (b) (4) **23 Sep 2020 15:17:42**
Generated On: 10 Jun 2021 08:13:30

Was the physical examination performed?	Yes ■ No ☐
Date of examination *(dd MMM yyyy)*	21 SEP 2020

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

FDA-CBER-2022-1614-2659608

US3542053
Folder: Visit 2 Day 29 (1)
Form: Exposure
Data signed: (b) (4) **23 Sep 2020 15:17:42**
Generated On: 10 Jun 2021 08:13:30

Was study treatment given?	Yes ■ No ☐
If No, reason not given	Participant declined due to Adverse Event ☐ Physician withheld dose due to Adverse Event ☐ Death ☐ Lost To Follow-Up ☐ Physician Decision ☐ Pregnancy ☐ Protocol Deviation ☐ Study Terminated by Sponsor ☐ Withdrawal of Consent by Participant ☐ Confirmed COVID-19 ☐ Other ☐
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment?	MRNA-1273 OR PLACEBO
What was the treatment date? *(dd MMM yyyy)*	21 SEP 2020
What was the treatment time? *(00:00-23:59)*	10:04 (24 HR)
Treatment Date and Time (derived)	21 SEP 2020 10:04
Which arm was used to give treatment?	Left Arm ■ Right Arm ☐
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

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US3542053
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **23 Sep 2020 15:17:42**
Generated On: 10 Jun 2021 08:13:30

Was the sample collected?	Yes ☑ No ☐
Collection date *(dd MMM yyyy)*	21 SEP 2020
Collection time *(00:00-23:59)*	09:28 (24 HR)
Collection date and time (derived)	21 SEP 2020 09:28

US3542053
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab
Data signed: (b) (4) **20 Nov 2020 04:10:23**
Generated On: 10 Jun 2021 08:13:30

Collection date *(dd MMM yyyy)*			21 SEP 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:38	21 SEP 2020 09:38
Nasopharyngeal Swab 2	No		

US3542053
Folder: Visit 2 Day 29 (1)
Form: Continuing
Data signed: (b) (4) **23 Sep 2020 15:17:42**
Generated On: 10 Jun 2021 08:13:30

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

FDA-CBER-2022-1614-2659612

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**	98.1 °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	21 SEP 2020 10:39
PC Open Date & Time	21 SEP 2020 10:24
PC Close Date & Time	21 SEP 2020 12:54

US3542053
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 08:13:30

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**	97.1 °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	21 SEP 2020 21:32
PC Open Date & Time	21 SEP 2020 13:49
PC Close Date & Time	22 SEP 2020 11:59

US3542053
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 08:13:30

TIMEPOINT	DAY 2

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	97.5 °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	22 SEP 2020 21:53
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

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US3542053
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 08:13:30

TIMEPOINT	DAY 3

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	96.8 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	23 SEP 2020 21:38
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3542053
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 08:13:30

TIMEPOINT	DAY 4

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	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	24 SEP 2020 22:00
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3542053
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 08:13:30

TIMEPOINT	DAY 5

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	99.4 °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	25 SEP 2020 20:59
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

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US3542053
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 08:13:30

TIMEPOINT	DAY 6

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	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):	
To **TREAT** pain or fever that has already occurred	False
To **PREVENT** pain or fever from occurring	True
PC Time Stamp	26 SEP 2020 22:05
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

FDA-CBER-2022-1614-2659619

US3542053
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 08:13:30

TIMEPOINT	DAY 7

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	96.7 °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	28 SEP 2020 00:02
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

FDA-CBER-2022-1614-2659620

US3542053
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 08:13:30

TIMEPOINT	DAY 1, 30 MINUTES AFTER VACCINATION (AT STUDY CLINIC)
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	21 SEP 2020 10:40
PC Open Date & Time	21 SEP 2020 10:24
PC Close Date & Time	21 SEP 2020 12:54

US3542053
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 08:13:30

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	21 SEP 2020 21:32
PC Open Date & Time	21 SEP 2020 13:49
PC Close Date & Time	22 SEP 2020 11:59

US3542053
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 08:13:30

TIMEPOINT	DAY 2
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	22 SEP 2020 21:54
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3542053
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 08:13:30

TIMEPOINT	DAY 3
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	23 SEP 2020 21:38
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

FDA-CBER-2022-1614-2659624

US3542053
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 08:13:30

TIMEPOINT	DAY 4
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	24 SEP 2020 22:00
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3542053
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 08:13:30

TIMEPOINT	DAY 5
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	25 SEP 2020 20:59
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

FDA-CBER-2022-1614-2659626

US3542053
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 08:13:30

TIMEPOINT	DAY 6
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	26 SEP 2020 22:05
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3542053
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 08:13:30

TIMEPOINT	DAY 7
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	28 SEP 2020 00:02
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

FDA-CBER-2022-1614-2659628

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-2022-1614-2659629

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 08:13:30

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	21 SEP 2020 10:40
PC Open Date & Time	21 SEP 2020 10:24
PC Close Date & Time	21 SEP 2020 12:54

FDA-CBER-2022-1614-2659630

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-2022-1614-2659631

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 08:13:30

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	21 SEP 2020 21:33
PC Open Date & Time	21 SEP 2020 13:49
PC Close Date & Time	22 SEP 2020 11:59

FDA-CBER-2022-1614-2659632

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 08:13:30

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

FDA-CBER-2022-1614-2659633

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 08:13:30

	Yes ☐
PC Time stamp	22 SEP 2020 21:54
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

FDA-CBER-2022-1614-2659634

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 08:13:30

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

FDA-CBER-2022-1614-2659635

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 08:13:30

	Yes ☐
PC Time stamp	23 SEP 2020 21:39
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

FDA-CBER-2022-1614-2659636

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 08:13:30

TIMEPOINT	DAY 4
HEADACHE	None ■ No interference with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
FATIGUE	None ■ No interference with activity ☐ Some interference with activity ☐ Significant; prevents daily activity ☐
MUSCLE ACHES ALL OVER BODY	None ■ No interference with activity ☐ Some interference with activity ☐ Significant; prevents daily activity ☐
JOINT ACHES IN SEVERAL JOINTS	None ■ No interference with activity ☐ Some interference with activity ☐ Significant; prevents daily activity ☐
NAUSEA/VOMITING	None ■ No interference with activity or 1-2 episodes/24 hours ☐ Some interference with activity or >2 episodes/24 hours ☐ Prevents daily activity, requires outpatient IV hydration ☐
CHILLS	None ■ No interference with activity ☐ Some interference with activity not requiring medical attention ☐ Prevents daily activity and requires medical attention ☐
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■

FDA-CBER-2022-1614-2659637

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 08:13:30

	Yes ☐
PC Time stamp	24 SEP 2020 22:00
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

FDA-CBER-2022-1614-2659638

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 08:13:30

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-2022-1614-2659639

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 08:13:30

	Yes ☐
PC Time stamp	25 SEP 2020 21:02
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

FDA-CBER-2022-1614-2659640

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 08:13:30

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

FDA-CBER-2022-1614-2659641

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 08:13:30

	Yes
PC Time stamp	26 SEP 2020 22:06
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

FDA-CBER-2022-1614-2659642

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 08:13:30

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

FDA-CBER-2022-1614-2659643

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 08:13:30

	Yes ☐
PC Time stamp	28 SEP 2020 00:03
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

FDA-CBER-2022-1614-2659644

US3542053
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(8)
Generated On: 10 Jun 2021 08:13:30

TIMEPOINT	DAY 8
Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**	None ☐ No interference with activity ☐ Some interference with activity ☐ Significant; prevents daily activity ☐
PC Time stamp	
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

FDA-CBER-2022-1614-2659645

US3542053
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(9)
Generated On: 10 Jun 2021 08:13:30

TIMEPOINT	DAY 9
Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**	None ■ No interference with activity ☐ Some interference with activity ☐ Significant; prevents daily activity ☐
PC Time stamp	29 SEP 2020 22:49
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

FDA-CBER-2022-1614-2659646

US3542053
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(8)
Generated On: 10 Jun 2021 08:13:30

TIMEPOINT	DAY 8
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ☐ Yes ☐
PC Time stamp	
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

FDA-CBER-2022-1614-2659647

US3542053
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(9)
Generated On: 10 Jun 2021 08:13:30

TIMEPOINT	DAY 9
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	29 SEP 2020 22:49
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

FDA-CBER-2022-1614-2659648

US3542053
Folder: Safety Call Day 36 (1)
Form: Safety Call
Data signed: (b) (4) **30 Sep 2020 22:38:17**
Generated On: 10 Jun 2021 08:13:30

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-2022-1614-2659649

US3542053
Folder: Safety Call Day 36 (1)
Form: Continuing
Data signed: (b) (4) **30 Sep 2020 22:38:17**
Generated On: 10 Jun 2021 08:13:30

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

FDA-CBER-2022-1614-2659650

US3542053
Folder: Safety Call Day 43 (1)
Form: Safety Call
Data signed: (b) (4) **08 Oct 2020 02:55:31**
Generated On: 10 Jun 2021 08:13:30

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	6 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-2022-1614-2659651

US3542053
Folder: Safety Call Day 43 (1)
Form: Continuing
Data signed: (b) (4) **08 Oct 2020 02:55:31**
Generated On: 10 Jun 2021 08:13:30

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

FDA-CBER-2022-1614-2659652

US3542053
Folder: Safety Call Day 50 (1)
Form: Safety Call
Data signed: (b) (4) **16 Oct 2020 02:46:06**
Generated On: 10 Jun 2021 08:13:30

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-2022-1614-2659653

US3542053
Folder: Safety Call Day 50 (1)
Form: Continuing
Data signed: (b) (4) **16 Oct 2020 02:46:06**
Generated On: 10 Jun 2021 08:13:30

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

FDA-CBER-2022-1614-2659654

US3542053
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Data signed: (b) (4) **21 Oct 2020 18:32:30**
Generated On: 10 Jun 2021 08:13:30

Was this visit performed?	Yes ☑ No ☐
Visit date (dd MMM yyyy)	21 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ☑
Folder OID	VISIT3

FDA-CBER-2022-1614-2659655

US3542053
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Data signed: (b) (4) **21 Oct 2020 18:32:30**
Generated On: 10 Jun 2021 08:13:30

Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	21 OCT 2020
Time of assessment *(00:00-23:59)*	09:07 (24 HR)
Vital Signs Date and Time (derived)	21 OCT 2020 09:07
Temperature *(xxx.x)*	98.3 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	75 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	75 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

FDA-CBER-2022-1614-2659656

US3542053
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Data signed: (b) (4) **21 Oct 2020 18:32:30**
Generated On: 10 Jun 2021 08:13:30

Was the physical examination performed? Yes ☐ No ■

Date of examination *(dd MMM yyyy)* _____

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

FDA-CBER-2022-1614-2659657

US3542053
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **21 Oct 2020 18:32:30**
Generated On: 10 Jun 2021 08:13:30

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	21 OCT 2020
Collection time *(00:00-23:59)*	09:01 (24 HR)
Collection date and time (derived)	21 OCT 2020 09:01

FDA-CBER-2022-1614-2659658

US3542053
Folder: Visit 3 Day 57 (1)
Form: Continuing
Data signed: (b) (4) **21 Oct 2020 18:32:30**
Generated On: 10 Jun 2021 08:13:30

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

FDA-CBER-2022-1614-2659659

US3542053
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-2659660

US3542053
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	25 OCT 2020 00:01
Patient Cloud Close Date & Time	29 OCT 2020 23:59

FDA-CBER-2022-1614-2659661

US3542053
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 NOV 2020 11:54:23
Patient Cloud Open Date & Time	01 NOV 2020 00:01
Patient Cloud Close Date & Time	05 NOV 2020 23:59

US3542053
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 NOV 2020 12:14:08
Patient Cloud Open Date & Time	08 NOV 2020 00:01
Patient Cloud Close Date & Time	12 NOV 2020 23:59

FDA-CBER-2022-1614-2659663

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 NOV 2020 00:34:49
Patient Cloud Open Date & Time	19 NOV 2020 00:01
Patient Cloud Close Date & Time	23 NOV 2020 23:59

FDA-CBER-2022-1614-2659664

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	26 NOV 2020 00:02:22
Patient Cloud Open Date & Time	26 NOV 2020 00:01
Patient Cloud Close Date & Time	30 NOV 2020 23:59

FDA-CBER-2022-1614-2659665

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 DEC 2020 00:02:00
Patient Cloud Open Date & Time	03 DEC 2020 00:01
Patient Cloud Close Date & Time	07 DEC 2020 23:59

FDA-CBER-2022-1614-2659666

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 DEC 2020 00:09:32
Patient Cloud Open Date & Time	10 DEC 2020 00:01
Patient Cloud Close Date & Time	14 DEC 2020 23:59

FDA-CBER-2022-1614-2659667

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ■
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ■
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ■
Date and time of submission	17 DEC 2020 00:19:52
Patient Cloud Open Date & Time	17 DEC 2020 00:01
Patient Cloud Close Date & Time	21 DEC 2020 23:59

FDA-CBER-2022-1614-2659668

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-2659669

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	24 DEC 2020 00:01
Patient Cloud Close Date & Time	28 DEC 2020 23:59

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 JAN 2021 12:00:00
Patient Cloud Open Date & Time	31 DEC 2020 00:01
Patient Cloud Close Date & Time	04 JAN 2021 23:59

FDA-CBER-2022-1614-2659671

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 JAN 2021 18:07:20
Patient Cloud Open Date & Time	07 JAN 2021 00:01
Patient Cloud Close Date & Time	11 JAN 2021 23:59

FDA-CBER-2022-1614-2659672

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 JAN 2021 00:01:51
Patient Cloud Open Date & Time	14 JAN 2021 00:01
Patient Cloud Close Date & Time	18 JAN 2021 23:59

FDA-CBER-2022-1614-2659673

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

FDA-CBER-2022-1614-2659674

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	21 JAN 2021 00:01
Patient Cloud Close Date & Time	25 JAN 2021 23:59

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 JAN 2021 00:23:28
Patient Cloud Open Date & Time	28 JAN 2021 00:01
Patient Cloud Close Date & Time	01 FEB 2021 23:59

FDA-CBER-2022-1614-2659676

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 FEB 2021 00:01:41
Patient Cloud Open Date & Time	04 FEB 2021 00:01
Patient Cloud Close Date & Time	08 FEB 2021 23:59

FDA-CBER-2022-1614-2659677

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

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

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 FEB 2021 12:16:48
Patient Cloud Open Date & Time	18 FEB 2021 00:01
Patient Cloud Close Date & Time	22 FEB 2021 23:59

FDA-CBER-2022-1614-2659680

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	25 FEB 2021 00:05:18
Patient Cloud Open Date & Time	25 FEB 2021 00:01
Patient Cloud Close Date & Time	01 MAR 2021 23:59

FDA-CBER-2022-1614-2659681

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 MAR 2021 12:18:00
Patient Cloud Open Date & Time	04 MAR 2021 00:01
Patient Cloud Close Date & Time	08 MAR 2021 23:59

FDA-CBER-2022-1614-2659682

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 MAR 2021 00:14:04
Patient Cloud Open Date & Time	11 MAR 2021 00:01
Patient Cloud Close Date & Time	15 MAR 2021 23:59

FDA-CBER-2022-1614-2659683

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30

TIMEPOINT	DAY 208
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 MAR 2021 18:01:14
Patient Cloud Open Date & Time	18 MAR 2021 00:01
Patient Cloud Close Date & Time	22 MAR 2021 23:59

FDA-CBER-2022-1614-2659684

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	25 MAR 2021 00:05:41
Patient Cloud Open Date & Time	25 MAR 2021 00:01
Patient Cloud Close Date & Time	29 MAR 2021 23:59

FDA-CBER-2022-1614-2659685

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 APR 2021 00:08:35
Patient Cloud Open Date & Time	01 APR 2021 00:01
Patient Cloud Close Date & Time	05 APR 2021 23:59

FDA-CBER-2022-1614-2659686

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 APR 2021 21:04:15
Patient Cloud Open Date & Time	08 APR 2021 00:01
Patient Cloud Close Date & Time	12 APR 2021 23:59

FDA-CBER-2022-1614-2659687

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 APR 2021 07:02:59
Patient Cloud Open Date & Time	15 APR 2021 00:01
Patient Cloud Close Date & Time	19 APR 2021 23:59

FDA-CBER-2022-1614-2659688

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

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

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 MAY 2021 13:19:22
Patient Cloud Open Date & Time	29 APR 2021 00:01
Patient Cloud Close Date & Time	03 MAY 2021 23:59

FDA-CBER-2022-1614-2659691

TIMEPOINT	DAY 257
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-2659692

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

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

FDA-CBER-2022-1614-2659694

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

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-2659696

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

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

FDA-CBER-2022-1614-2659698

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	27 MAY 2021 00:01
Patient Cloud Close Date & Time	31 MAY 2021 23:59

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

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

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-2659702

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30

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

TIMEPOINT	DAY 299
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

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

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

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

TIMEPOINT	DAY 313
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

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

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

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

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-2659712

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

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

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

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

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30

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

FDA-CBER-2022-1614-2659717

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

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

TIMEPOINT	DAY 355
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

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

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

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

TIMEPOINT	DAY 369
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-2659724

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

FDA-CBER-2022-1614-2659725

TIMEPOINT	DAY 376
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	02 SEP 2021 00:01
Patient Cloud Close Date & Time	06 SEP 2021 23:59

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

FDA-CBER-2022-1614-2659728

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

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	16 SEP 2021 00:01
Patient Cloud Close Date & Time	20 SEP 2021 23:59

TIMEPOINT	DAY 397
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-2659732

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

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-2659734

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	30 SEP 2021 00:01
Patient Cloud Close Date & Time	04 OCT 2021 23:59

TIMEPOINT	DAY 411
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-2659736

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	07 OCT 2021 00:01
Patient Cloud Close Date & Time	11 OCT 2021 23:59

FDA-CBER-2022-1614-2659737

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-2659738

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	14 OCT 2021 00:01
Patient Cloud Close Date & Time	18 OCT 2021 23:59

FDA-CBER-2022-1614-2659739

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-2659740

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	21 OCT 2021 00:01
Patient Cloud Close Date & Time	25 OCT 2021 23:59

FDA-CBER-2022-1614-2659741

TIMEPOINT	DAY 432
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-2659742

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30

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

FDA-CBER-2022-1614-2659743

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

FDA-CBER-2022-1614-2659744

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

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30

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

FDA-CBER-2022-1614-2659746

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

FDA-CBER-2022-1614-2659747

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

FDA-CBER-2022-1614-2659748

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

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-2659750

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

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	02 DEC 2021 00:01
Patient Cloud Close Date & Time	06 DEC 2021 23:59

FDA-CBER-2022-1614-2659753

TIMEPOINT	DAY 474
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-2659754

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

TIMEPOINT	DAY 481
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-2659756

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	16 DEC 2021 00:01
Patient Cloud Close Date & Time	20 DEC 2021 23:59

FDA-CBER-2022-1614-2659757

TIMEPOINT	DAY 488
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-2659758

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

FDA-CBER-2022-1614-2659759

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	30 DEC 2021 00:01
Patient Cloud Close Date & Time	03 JAN 2022 23:59

TIMEPOINT	DAY 502
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-2659762

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	06 JAN 2022 00:01
Patient Cloud Close Date & Time	10 JAN 2022 23:59

TIMEPOINT	DAY 509
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-2659764

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

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-2659766

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	20 JAN 2022 00:01
Patient Cloud Close Date & Time	24 JAN 2022 23:59

TIMEPOINT	DAY 523
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-2659768

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

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30

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

FDA-CBER-2022-1614-2659771

TIMEPOINT	DAY 537
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	10 FEB 2022 00:01
Patient Cloud Close Date & Time	14 FEB 2022 23:59

FDA-CBER-2022-1614-2659773

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	17 FEB 2022 00:01
Patient Cloud Close Date & Time	21 FEB 2022 23:59

TIMEPOINT	DAY 551
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

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

FDA-CBER-2022-1614-2659777

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30

TIMEPOINT	DAY 558
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-2659778

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30

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

FDA-CBER-2022-1614-2659779

TIMEPOINT	DAY 565
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	10 MAR 2022 00:01
Patient Cloud Close Date & Time	14 MAR 2022 23:59

TIMEPOINT	DAY 572
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	17 MAR 2022 00:01
Patient Cloud Close Date & Time	21 MAR 2022 23:59

TIMEPOINT	DAY 579
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-2659784

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

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

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

FDA-CBER-2022-1614-2659787

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30

TIMEPOINT	DAY 593
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-2659788

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	07 APR 2022 00:01
Patient Cloud Close Date & Time	11 APR 2022 23:59

FDA-CBER-2022-1614-2659789

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	14 APR 2022 00:01
Patient Cloud Close Date & Time	18 APR 2022 23:59

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	21 APR 2022 00:01
Patient Cloud Close Date & Time	25 APR 2022 23:59

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-2659794

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	28 APR 2022 00:01
Patient Cloud Close Date & Time	02 MAY 2022 23:59

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-2659796

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	05 MAY 2022 00:01
Patient Cloud Close Date & Time	09 MAY 2022 23:59

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	12 MAY 2022 00:01
Patient Cloud Close Date & Time	16 MAY 2022 23:59

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	19 MAY 2022 00:01
Patient Cloud Close Date & Time	23 MAY 2022 23:59

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-2659802

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	26 MAY 2022 00:01
Patient Cloud Close Date & Time	30 MAY 2022 23:59

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-2659804

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	02 JUN 2022 00:01
Patient Cloud Close Date & Time	06 JUN 2022 23:59

FDA-CBER-2022-1614-2659805

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

FDA-CBER-2022-1614-2659806

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

TIMEPOINT	DAY 663
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-2659808

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	16 JUN 2022 00:01
Patient Cloud Close Date & Time	20 JUN 2022 23:59

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

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

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	30 JUN 2022 00:01
Patient Cloud Close Date & Time	04 JUL 2022 23:59

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	07 JUL 2022 00:01
Patient Cloud Close Date & Time	11 JUL 2022 23:59

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	14 JUL 2022 00:01
Patient Cloud Close Date & Time	18 JUL 2022 23:59

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	21 JUL 2022 00:01
Patient Cloud Close Date & Time	25 JUL 2022 23:59

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

FDA-CBER-2022-1614-2659820

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

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-2659822

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	04 AUG 2022 00:01
Patient Cloud Close Date & Time	08 AUG 2022 23:59

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-2659824

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	11 AUG 2022 00:01
Patient Cloud Close Date & Time	15 AUG 2022 23:59

FDA-CBER-2022-1614-2659825

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-2659826

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

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-2659828

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	25 AUG 2022 00:01
Patient Cloud Close Date & Time	29 AUG 2022 23:59

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-2659830

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	01 SEP 2022 00:01
Patient Cloud Close Date & Time	05 SEP 2022 23:59

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-2659832

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	08 SEP 2022 00:01
Patient Cloud Close Date & Time	12 SEP 2022 23:59

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-2659834

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	15 SEP 2022 00:01
Patient Cloud Close Date & Time	19 SEP 2022 23:59

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-2659836

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

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

FDA-CBER-2022-1614-2659838

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	29 SEP 2022 00:01
Patient Cloud Close Date & Time	03 OCT 2022 23:59

TIMEPOINT	DAY 775
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-2659840

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	06 OCT 2022 00:01
Patient Cloud Close Date & Time	10 OCT 2022 23:59

FDA-CBER-2022-1614-2659841

TIMEPOINT	DAY 782
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-2659842

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

TIMEPOINT	DAY 789
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-2659844

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	20 OCT 2022 00:01
Patient Cloud Close Date & Time	24 OCT 2022 23:59

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-2659846

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

FDA-CBER-2022-1614-2659847

US3542053
Folder: Cosmetic Injections and Dermal Fillers
Form: Cosmetic Injection_ Dermal Filler eDiary
Generated On: 10 Jun 2021 08:13:30

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		08 MAR 2021 12:18:24

US3542053
Folder: Safety Call Day 85 (1)
Form: Safety Call
Data signed: (b) (4) **20 Nov 2020 04:10:23**
Generated On: 10 Jun 2021 08:13:30

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

FDA-CBER-2022-1614-2659849

US3542053
Folder: Safety Call Day 85 (1)
Form: Continuing
Data signed: (b) (4) **20 Nov 2020 04:10:23**
Generated On: 10 Jun 2021 08:13:30

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

FDA-CBER-2022-1614-2659850

US3542053
Folder: Safety Call Day 119 (1)
Form: Safety Call
Data signed: (b) (4) **27 Dec 2020 22:58:26**
Generated On: 10 Jun 2021 08:13:30

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	17 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-2022-1614-2659851

US3542053
Folder: Safety Call Day 119 (1)
Form: Continuing
Data signed: (b) (4) **27 Dec 2020 22:58:26**
Generated On: 10 Jun 2021 08:13:30

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

FDA-CBER-2022-1614-2659852

US3542053
Folder: Safety Call Day 149 (1)
Form: Safety Call
Data signed: (b) (4) **22 Jan 2021 18:10:54**
Generated On: 10 Jun 2021 08:13:30

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	16 JAN 2021
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments *If Contact Not Made, please provide Comments*	

FDA-CBER-2022-1614-2659853

US3542053
Folder: Safety Call Day 149 (1)
Form: Continuing
Data signed: (b) (4) **22 Jan 2021 18:10:54**
Generated On: 10 Jun 2021 08:13:30

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

FDA-CBER-2022-1614-2659854

US3542053
Folder: Safety Call Day 179 (1)
Form: Safety Call
Data signed: (b) (4) **23 Feb 2021 16:40:27**
Generated On: 10 Jun 2021 08:13:30

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	17 FEB 2021
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments *If Contact Not Made, please provide Comments*	

FDA-CBER-2022-1614-2659855

US3542053
Folder: Safety Call Day 179 (1)
Form: Continuing
Data signed: (b) (4) **23 Feb 2021 16:40:27**
Generated On: 10 Jun 2021 08:13:30

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

FDA-CBER-2022-1614-2659856

US3542053
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Data signed: (b) (4) **26 Mar 2021 16:51:28**
Generated On: 10 Jun 2021 08:13:30

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	24 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	VISIT4

FDA-CBER-2022-1614-2659857

US3542053
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Data signed: (b) (4) **31 Mar 2021 21:13:49**
Generated On: 10 Jun 2021 08:13:30

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

FDA-CBER-2022-1614-2659858

US3542053
Folder: Visit 4 Day 209 (1)
Form: Physical Examination
Data signed: (b) (4) **26 Mar 2021 16:51:28**
Generated On: 10 Jun 2021 08:13:30

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

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

FDA-CBER-2022-1614-2659859

US3542053
Folder: Visit 4 Day 209 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **26 Mar 2021 16:51:28**
Generated On: 10 Jun 2021 08:13:30

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	24 MAR 2021
Collection time *(00:00-23:59)*	09:03 (24 HR)
Collection date and time (derived)	24 MAR 2021 09:03

FDA-CBER-2022-1614-2659860

US3542053
Folder: Visit 4 Day 209 (1)
Form: Continuing
Data signed: (b) (4) **26 Mar 2021 16:51:28**
Generated On: 10 Jun 2021 08:13:30

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

FDA-CBER-2022-1614-2659861

US3542053
Folder: Safety Call Day 239 (1)
Form: Safety Call
Data signed: (b) (4) **20 Apr 2021 12:55:28**
Generated On: 10 Jun 2021 08:13:30

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	16 APR 2021
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments *If Contact Not Made, please provide Comments*	

FDA-CBER-2022-1614-2659862

US3542053
Folder: Safety Call Day 239 (1)
Form: Continuing
Data signed: (b) (4) **20 Apr 2021 12:55:28**
Generated On: 10 Jun 2021 08:13:30

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

FDA-CBER-2022-1614-2659863

US3542053
Folder: Safety Call Day 269 (1)
Form: Safety Call
Generated On: 10 Jun 2021 08:13:30

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

FDA-CBER-2022-1614-2659864

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

US3542053
Folder: Covid-19 Assessment (1)
Form: COVID-19 Contact
Generated On: 10 Jun 2021 08:13:30

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-2022-1614-2659866

Generate Next COVID-19 Assessment	Yes ☐ No ☐

US3542053
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Data signed: (b) (4) **13 Jan 2021 03:41:29**
Generated On: 10 Jun 2021 08:13:30

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	08 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	UNBLND_DECIDE

FDA-CBER-2022-1614-2659868

US3542053
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Data signed: (b) (4) **12 Mar 2021 22:39:58**
Generated On: 10 Jun 2021 08:13:30

Date of updated informed consent *(dd MMM yyyy)*	08 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes ■ No ☐
Under what version of the Protocol was the Participant unblinded?	Amendment 5 ☐ Amendment 6 or later ■
Date of unblinding *(dd MMM yyyy)*	08 JAN 2021
Participant randomization assignment	mRNA-1273 ☐ Placebo ■
Actual Dose 1	mRNA-1273 ☐ Placebo ■ Not Administered ☐
Actual Dose 2	mRNA-1273 ☐ Placebo ■ Not Administered ☐
Will participant receive mRNA-1273?	Yes ■ No ☐
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3542053
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Data signed: (b) (4) **13 Jan 2021 03:41:29**
Generated On: 10 Jun 2021 08:13:30

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

FDA-CBER-2022-1614-2659870

US3542053
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Data signed: (b) (4) **13 Jan 2021 03:41:29**
Generated On: 10 Jun 2021 08:13:30

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose ●
	Post-Dose ○
Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	08 JAN 2021
Time of assessment *(00:00-23:59)*	09:35 (24 HR)
Vital Signs Date and Time (derived)	08 JAN 2021 09:35
Temperature *(xxx.x)*	98.2 F
Route of measurement	Oral ●
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	79 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	64 mmHg
Diastolic Blood Pressure units	MMHG

US3542053
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Data signed: (b) (4) **13 Jan 2021 03:41:29**
Generated On: 10 Jun 2021 08:13:30

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose ☐ Post-Dose ■
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	08 JAN 2021
Time of assessment *(00:00-23:59)*	10:25 (24 HR)
Vital Signs Date and Time (derived)	08 JAN 2021 10:25
Temperature *(xxx.x)*	98.2 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	78 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	80 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-2659872

US3542053
Folder: Participant Decision Visit / OL-D1 (1)
Form: Physical Examination
Data signed: (b) (4) **13 Jan 2021 03:41:29**
Generated On: 10 Jun 2021 08:13:30

Was the physical examination performed?	Yes ■ No ☐
Date of examination *(dd MMM yyyy)*	08 JAN 2021

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

FDA-CBER-2022-1614-2659873

US3542053
Folder: Participant Decision Visit / OL-D1 (1)
Form: Exposure
Data signed: (b) (4) **13 Jan 2021 03:41:29**
Generated On: 10 Jun 2021 08:13:30

Was study treatment given?	Yes ■ No ☐
If No, reason not given	Participant declined due to Adverse Event ☐ Physician withheld dose due to Adverse Event ☐ Death ☐ Lost To Follow-Up ☐ Physician Decision ☐ Pregnancy ☐ Protocol Deviation ☐ Study Terminated by Sponsor ☐ Withdrawal of Consent by Participant ☐ Confirmed COVID-19 ☐ Other ☐
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment? (Unblinded)	MRNA-1273
What was the treatment date? *(dd MMM yyyy)*	08 JAN 2021
What was the treatment time? *(00:00-23:59)*	09:55 (24 HR)
Treatment Date and Time (derived)	08 JAN 2021 09:55
Which arm was used to give treatment?	Left Arm ■ Right Arm ☐
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

FDA-CBER-2022-1614-2659874

US3542053
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **13 Jan 2021 03:41:29**
Generated On: 10 Jun 2021 08:13:30

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	08 JAN 2021
Collection time *(00:00-23:59)*	09:45 (24 HR)
Collection date and time (derived)	08 JAN 2021 09:45

FDA-CBER-2022-1614-2659875

US3542053
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Data signed: (b) (4) **13 Jan 2021 03:41:29**
Generated On: 10 Jun 2021 08:13:30

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	08 JAN 2021
Collection time *(00:00 - 23:59)*	09:51
Collection Date and Time (derived)	08 JAN 2021 09:51

FDA-CBER-2022-1614-2659876

US3542053
Folder: Participant Decision Visit / OL-D1 (1)
Form: Continuing
Data signed: (b) (4) **13 Jan 2021 03:41:29**
Generated On: 10 Jun 2021 08:13:30

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

FDA-CBER-2022-1614-2659877

US3542053
Folder: Safety Call OL-D8 (1)
Form: Safety Call
Data signed: (b) (4) **22 Jan 2021 18:10:54**
Generated On: 10 Jun 2021 08:13:30

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	15 JAN 2021
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments *If Contact Not Made, please provide Comments*	

FDA-CBER-2022-1614-2659878

US3542053
Folder: Safety Call OL-D8 (1)
Form: Continuing
Data signed: (b) (4) **22 Jan 2021 18:10:54**
Generated On: 10 Jun 2021 08:13:30

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1
OLD29 Placebo Flag	1

FDA-CBER-2022-1614-2659879

US3542053
Folder: OL-D29 (1)
Form: Visit Date
Data signed: (b) (4) **05 Mar 2021 14:54:22**
Generated On: 10 Jun 2021 08:13:30

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	25 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	OLD29

FDA-CBER-2022-1614-2659880

US3542053
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Data signed: (b) (4) **05 Mar 2021 14:54:22**
Generated On: 10 Jun 2021 08:13:30

Timepoint	Pre-Dose ■ Post-Dose ☐
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	25 FEB 2021
Time of assessment *(00:00-23:59)*	09:19 (24 HR)
Vital Signs Date and Time (derived)	25 FEB 2021 09:19
Temperature *(xxx.x)*	98.0 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	55 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	64 mmHg
Diastolic Blood Pressure units	MMHG

US3542053
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Data signed: (b) (4) **05 Mar 2021 14:54:22**
Generated On: 10 Jun 2021 08:13:30

Timepoint	Pre-Dose ☐ Post-Dose ■
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	25 FEB 2021
Time of assessment *(00:00-23:59)*	10:25 (24 HR)
Vital Signs Date and Time (derived)	25 FEB 2021 10:25
Temperature *(xxx.x)*	98.2 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	53 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	65 mmHg
Diastolic Blood Pressure units	MMHG

US3542053
Folder: OL-D29 (1)
Form: Physical Examination
Data signed: (b) (4) **05 Mar 2021 14:54:22**
Generated On: 10 Jun 2021 08:13:30

Was the physical examination performed?	Yes ☑ No ☐
Date of examination *(dd MMM yyyy)*	25 FEB 2021

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

FDA-CBER-2022-1614-2659883

US3542053
Folder: OL-D29 (1)
Form: Exposure
Data signed: (b) (4) **05 Mar 2021 14:54:22**
Generated On: 10 Jun 2021 08:13:30

Was study treatment given?	Yes ■ No ☐
If No, reason not given	Participant declined due to Adverse Event ☐ Physician withheld dose due to Adverse Event ☐ Death ☐ Lost To Follow-Up ☐ Physician Decision ☐ Pregnancy ☐ Protocol Deviation ☐ Study Terminated by Sponsor ☐ Withdrawal of Consent by Participant ☐ Confirmed COVID-19 ☐ Other ☐
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment? (Unblinded)	MRNA-1273
What was the treatment date? *(dd MMM yyyy)*	25 FEB 2021
What was the treatment time? *(00:00-23:59)*	09:55 (24 HR)
Treatment Date and Time (derived)	25 FEB 2021 09:55
Which arm was used to give treatment?	Left Arm ■ Right Arm ☐
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

FDA-CBER-2022-1614-2659884

US3542053
Folder: OL-D29 (1)
Form: Continuing
Data signed: (b) (4) **05 Mar 2021 14:54:22**
Generated On: 10 Jun 2021 08:13:30

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

FDA-CBER-2022-1614-2659885

US3542053
Folder: Safety Call OL-D36 (1)
Form: Safety Call
Data signed: (b) (4) **09 Mar 2021 04:08:47**
Generated On: 10 Jun 2021 08:13:30

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	05 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-2022-1614-2659886

US3542053
Folder: Safety Call OL-D36 (1)
Form: Continuing
Data signed: (b) (4) **09 Mar 2021 04:08:47**
Generated On: 10 Jun 2021 08:13:30

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

FDA-CBER-2022-1614-2659887

US3542053
Folder: OL-D57 (1)
Form: Visit Date
Data signed: (b) (4) **26 Mar 2021 16:51:28**
Generated On: 10 Jun 2021 08:13:30

Was this visit performed?	Yes ☑ No ☐
Visit date (dd MMM yyyy)	24 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ☑
Folder OID	OLD57

FDA-CBER-2022-1614-2659888

US3542053
Folder: OL-D57 (1)
Form: Vital Signs
Data signed: (b) (4) **26 Mar 2021 16:51:28**
Generated On: 10 Jun 2021 08:13:30

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

FDA-CBER-2022-1614-2659889

US3542053
Folder: OL-D57 (1)
Form: Physical Examination
Data signed: (b) (4) **26 Mar 2021 16:51:28**
Generated On: 10 Jun 2021 08:13:30

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

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

FDA-CBER-2022-1614-2659890

US3542053
Folder: OL-D57 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **26 Mar 2021 16:51:28**
Generated On: 10 Jun 2021 08:13:30

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	24 MAR 2021
Collection time *(00:00-23:59)*	09:03 (24 HR)
Collection date and time (derived)	24 MAR 2021 09:03

FDA-CBER-2022-1614-2659891

US3542053
Folder: Adverse Events
Form: Adverse Events Summary
Data signed: (b) (4) **30 Sep 2020 22:38:17**
Generated On: 10 Jun 2021 08:13:30

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

If Yes, enter details on the Adverse Events form.

FDA-CBER-2022-1614-2659892

US3542053
Folder: Adverse Events
Form: Adverse Events (1)
Data signed: (b) (4) **12 Mar 2021 22:39:58**
Generated On: 10 Jun 2021 08:13:30

AEID	
Adverse event	BACK PAIN, LOWER
Was this a medically-attended AE?	Yes ■ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ■
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ■
Start date *(dd MMM yyyy)*	25 SEP 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ■
If not Ongoing, end date *(dd MMM yyyy)*	2 OCT 2020
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ■ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ■
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ■ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ■ Related ☐ Not Applicable ☐
Action taken with investigational product	None ■ Dose Delayed ☐ Investigational Product Withdrawn ☐ Not Applicable ☐
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ■ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Ony)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3542053
Folder: Adverse Events
Form: Adverse Events (2)
Data signed: (b) (4) **12 Mar 2021 22:39:58**
Generated On: 10 Jun 2021 08:13:30

AEID	
Adverse event	DIZZINESS
Was this a medically-attended AE?	Yes ☐ No ■
Was this a Solicited Adverse Reaction?	Yes ☐ No ■
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ■
Start date *(dd MMM yyyy)*	20 OCT 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ■
If not Ongoing, end date *(dd MMM yyyy)*	20 OCT 2020
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ■ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ■
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	

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Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ■ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ■ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product Withdrawn ☐ Not Applicable ■
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ■ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Ony)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3542053
Folder: Adverse Events
Form: Adverse Events (3)
Data signed: (b) (4) **12 Mar 2021 22:39:58**
Generated On: 10 Jun 2021 08:13:30

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

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ■ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ■ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product Withdrawn ☐ Not Applicable ■
Other action taken (check all that apply)	
None	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	
Serious Adverse Event Derived (CSA Programming Field Ony)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3542053
Folder: Adverse Events
Form: Adverse Events (4)
Data signed: (b) (4) **12 Mar 2021 22:39:58**
Generated On: 10 Jun 2021 08:13:30

AEID	USA-US084-2021-MRNA-1273-P30 1000004
Adverse event	ATRIAL FLUTTER
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)*	04 FEB 2021
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ■
If not Ongoing, end date *(dd MMM yyyy)*	08 FEB 2021
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ■ Grade 4 ☐
Is the adverse event serious?	Yes ■ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date *(dd MMM yyyy)*	04 FEB 2021
Hospital Discharge Date *(dd MMM yyyy)*	08 FEB 2021
Admitted to ICU?	Yes ☐ No ■ Unknown ☐

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

	PT PRESENTED TO ED ON 4-FEB-2021 WITH TACHYCARDIA (160S), HEADACHE, DYSPNEA AND PALPITATIONS. PARTICIPANT WAS FOUND TO BE IN ATRIAL FLUTTER AND POSSIBLE ACUTE HEART FAILURE AND WAS ADMITTED FOR FURTHER MANAGEMENT AND OBSERVATION. PARTICIPANT HAD ELEVATED BNP AND EVIDENCE OF PULMONARY EDEMA ON CXR. ADMISSION COVID-19 PCR TEST ON 04FEB2021 WAS NEGATIVE. PARTICIPANT RECEIVED IV METOPROLOL WITH GOOD RESPONSE. SHE WAS RESTARTED ON PO METOPROLOL AND TRANSITIONED TO SOTALOL. SHE WAS GIVEN ONE DOSE OF IV LASIX WITH GOOD RESPONSE. PARTICIPANT UNDERWENT TTE ON 5-FEB-21 WHICH SHOWED EF 55-60%. TTE WAS REPEATED ON 7-FEB-21 AND SHOWED EF 50-55%. PARTICIPANT UNDERWENT CARDIOVERSION ON 8-FEB-21 AND WAS DISCHARGED LATER THAT DAY. PARTICIPANT HAS BEEN FEELING WELL OVERALL AND HAS REMAINED ASYMPTOMATIC SINCE 8-FEB-2021.
Serious Adverse Event Derived (CSA Programming Field Ony)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

US3542053
Folder: Adverse Events
Form: Adverse Events (5)
Data signed: (b) (4) **12 Mar 2021 22:39:58**
Generated On: 10 Jun 2021 08:13:30

AEID	
Adverse event	ACUTE HEART FAILURE
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)*	04 FEB 2021
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ■
If not Ongoing, end date *(dd MMM yyyy)*	08 FEB 2021
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ■ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ■
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ■ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ■ Related ☐ Not Applicable ☐
Action taken with investigational product	None ■ Dose Delayed ☐ Investigational Product Withdrawn ☐ Not Applicable ☐
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ■ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Ony)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination Summary
Data signed: (b) (4) **27 Aug 2020 15:41:44**
Generated On: 10 Jun 2021 08:13:30

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

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

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US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Data signed: (b) (4) **15 Mar 2021 20:17:40**
Generated On: 10 Jun 2021 08:13:30

Name of Medication	WARFARIN
Prophylaxis	Yes ☐ No ■
Indication	MITRAL VALVE REPLACEMENT
Dose per administration	6
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	ONCE MONDAY THROUGH SATURDAY
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 1984
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	05 FEB 2021
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☐

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Data signed: (b) (4) **15 Mar 2021 20:17:40**
Generated On: 10 Jun 2021 08:13:30

Name of Medication	WARFARIN
Prophylaxis	Yes ☐
	No ■
Indication	MITRAL VALVE REPLACEMENT
Dose per administration	7
Dose unit	mg ■
	ug ☐
	mL ☐
	g ☐
	IU ☐
	tablet ☐
	capsule ☐
	puff ☐
	Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐
	twice daily ☐
	three times daily ☐
	four times daily ☐
	every other day ☐
	every week ■
	every month ☐
	as needed ☐
	once ☐
	unknown ☐
	other ☐
If frequency is Other, specify	
Route of administration	Oral ■
	Topical ☐
	Subcutaneous ☐
	Transdermal ☐
	Intraocular ☐

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	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 1984
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	04 FEB 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 ☐

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Data signed: (b) (4) **15 Mar 2021 20:17:40**
Generated On: 10 Jun 2021 08:13:30

Name of Medication	FAMOTIDINE
Prophylaxis	Yes ☐ No ■
Indication	GASTRITIS
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-2022-1614-2659909

	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)*	13 SEP 2020
Start date completely unknown	False
Ongoing?	Yes ■
	No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Data signed: (b) (4) **15 Mar 2021 20:17:40**
Generated On: 10 Jun 2021 08:13:30

Name of Medication	OMEPRAZOLE
Prophylaxis	Yes ☐ No ■
Indication	GASTRITIS
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-2022-1614-2659911

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

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Data signed: (b) (4) **15 Mar 2021 20:17:40**
Generated On: 10 Jun 2021 08:13:30

Name of Medication	LIDOCAINE 5% PATCH
Prophylaxis	Yes ☐ No ■
Indication	BACK PAIN, LOWER
Dose per administration	ONE
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ■
If dose unit is Other, specify	APPLICATION
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-2022-1614-2659913

	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)*	26 SEP 2020
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	2 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 ■

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Data signed: (b) (4) **15 Mar 2021 20:17:40**
Generated On: 10 Jun 2021 08:13:30

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

	Intramuscular ■
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	24 OCT 2020
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	24 OCT 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 ☐

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Data signed: (b) (4) **15 Mar 2021 20:17:40**
Generated On: 10 Jun 2021 08:13:30

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

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	15 DEC 2020
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	23 DEC 2020
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

Name of Medication	OXYCODONE
Prophylaxis	Yes ☐ No ■
Indication	PAIN SECONDARY TO CHOLYSTECTOMY
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)*	16 DEC 2020
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	16 DEC 2020
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☐

Name of Medication	METOPROLOL
Prophylaxis	Yes ☐ No ■
Indication	ATRIAL FLUTTER
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)*	04 FEB 2021
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	04 FEB 2021
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☐

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Data signed: (b) (4) **15 Mar 2021 20:17:40**
Generated On: 10 Jun 2021 08:13:30

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

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	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	04 FEB 2021
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	08 FEB 2021
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 ■

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Data signed: (b) (4) **15 Mar 2021 20:17:40**
Generated On: 10 Jun 2021 08:13:30

Name of Medication	LASIX
Prophylaxis	Yes ☐ No ■
Indication	ACUTE HEART FAILURE
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-2022-1614-2659925

	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)*	04 FEB 2021
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	04 FEB 2021
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☐

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Data signed: (b) (4) **15 Mar 2021 20:17:40**
Generated On: 10 Jun 2021 08:13:30

Name of Medication	ATORVASTATIN
Prophylaxis	Yes ■ No ☐
Indication	CARDIAC HEALTH/ STROKE PREVENTION
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	QHS (NIGHTLY)
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)*	04 FEB 2021
Start date completely unknown	False
Ongoing?	Yes ■
	No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☐

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Data signed: (b) (4) **15 Mar 2021 20:17:40**
Generated On: 10 Jun 2021 08:13:30

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

	Intraocular ☐
	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	04 FEB 2021
Start date completely unknown	False
Ongoing?	Yes ■
	No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Data signed: (b) (4) **15 Mar 2021 20:17:40**
Generated On: 10 Jun 2021 08:13:30

Name of Medication	SOTALOL
Prophylaxis	Yes ☐ No ■
Indication	ATRIAL FLUTTER
Dose per administration	80
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-2022-1614-2659931

	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)*	07 FEB 2021
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	08 FEB 2021
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 ■

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Data signed: (b) (4) **15 Mar 2021 20:17:40**
Generated On: 10 Jun 2021 08:13:30

Name of Medication	SOTALOL
Prophylaxis	Yes ☐ No ■
Indication	ATRIAL FLUTER
Dose per administration	80
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)*	08 FEB 2021
Start date completely unknown	False
Ongoing?	Yes ■
	No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

FDA-CBER-2022-1614-2659934

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Data signed: (b) (4) **15 Mar 2021 20:17:40**
Generated On: 10 Jun 2021 08:13:30

Name of Medication	ENTRESTO
Prophylaxis	Yes ☐ No ■
Indication	ACUTE HEART FAILURE
Dose per administration	UNK
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ■
If dose unit is Other, specify	UNKNOWN
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-2022-1614-2659935

	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 FEB 2021
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	UN FEB 2021
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☐

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Data signed: (b) (4) **15 Mar 2021 20:17:40**
Generated On: 10 Jun 2021 08:13:30

Name of Medication	WARFARIN
Prophylaxis	Yes ☐ No ■
Indication	MITRAL VALVE REPLACEMENT
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-2022-1614-2659937

	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)*	05 FEB 2021
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	07 FEB 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 ■

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Data signed: (b) (4) **15 Mar 2021 20:17:40**
Generated On: 10 Jun 2021 08:13:30

Name of Medication	WARFARIN
Prophylaxis	Yes ☐ No ■
Indication	MITRAL VALVE REPLACEMENT
Dose per administration	6
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-2022-1614-2659939

	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 FEB 2021
Start date completely unknown	False
Ongoing?	Yes ■
	No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

US3542053
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures Summary
Data signed: (b) (4) **27 Dec 2020 22:58:26**
Generated On: 10 Jun 2021 08:13:30

Were any concomitant procedures performed?	Yes ■ No ☐

If yes, please complete Concomitant Procedures form.

FDA-CBER-2022-1614-2659941

US3542053
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures
Data signed: (b) (4) **05 Mar 2021 14:54:22**
Generated On: 10 Jun 2021 08:13:30

Procedure/Surgery date *(dd MMM yyyy)*	Procedure/Surgery	Indication	If indication is Other, specify
14 DEC 2020	CHOLECYSTECTOMY	Medical History	
15 DEC 2020	CARDIOVERSION	Adverse Event	
08 FEB 2021	CARDIOVERSION	Adverse Event	
05 FEB 2021	TTE WITH DOPPLER	Adverse Event	
07 FEB 2021	TTE WITH DOPPLER	Adverse Event	

FDA-CBER-2022-1614-2659942

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-2022-1614-2659943

US3542053
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 10 Jun 2021 08:13:30

Date of study discontinuation/completion *(dd MMM yyyy)*	
Reason for discontinuation	AE (specify) ☐ SAE (specify) ☐ Complete ☐ Death ☐ Lost To Follow-up ☐ Physician decision (specify) ☐ Pregnancy ☐ Protocol deviation (specify) ☐ Study Terminated By Sponsor ☐ Withdrawal of consent by participant (specify) ☐ Other ☐
If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify	
If reason for discontinuation is Death, main cause of death	Adverse event ☐ Unknown ☐ Other ☐
If main cause of death is Other, specify	
Date of death *(dd MMM yyyy)*	
Was autopsy performed?	Yes ☐ No ☐ Unknown ☐

US3542053
Folder: SAE USA-US084-2021-MRNA-1273-P301000004
Form: Safety Report Form
Data signed: (b) (4) **23 Feb 2021 16:40:27**
Generated On: 10 Jun 2021 08:13:30

SAEID	USA-US084-2021-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	DAVID
Investigator's Last Name	DIEMERT
Site Address: Street	2300 EYE STREET NW
Site Address: City	WASHINGTON
Site Address: State	
Site Address: Postal Code	20037
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3542053
Folder: SAE USA-US084-2021-MRNA-1273-P301000004
Form: Safety Report Form (1)
Data signed: (b) (4) **23 Feb 2021 16:40:27**
Generated On: 10 Jun 2021 08:13:30

SAEID	USA-US084-2021-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	DAVID
Investigator's Last Name	DIEMERT
Site Address: Street	2300 EYE STREET NW
Site Address: City	WASHINGTON
Site Address: State	
Site Address: Postal Code	20037
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	11/FEB/2021 14:23
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

FDA-CBER-2022-1614-2659946

US3542053
Folder: SAE USA-US084-2021-MRNA-1273-P301000004
Form: Safety Report Form (2)
Data signed: (b) (4) **23 Feb 2021 16:40:27**
Generated On: 10 Jun 2021 08:13:30

SAEID	USA-US084-2021-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	DAVID
Investigator's Last Name	DIEMERT
Site Address: Street	2300 EYE STREET NW
Site Address: City	WASHINGTON
Site Address: State	
Site Address: Postal Code	20037
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	22/FEB/2021 13:15
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-2022-1614-2659947

Audit

US3542053 (Prod: George Washington University)

US3542053
Form: Participant Creation
Generated On: 10 Jun 2021 08:13:30
Participant ID

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 16:51:31
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:41:44
User entered 'US3542053'	RWS_ENDPOINT ENDPOINT (b) (4)	25 Aug 2020 13:44:32

FDA-CBER-2022-1614-2659949

US3542053
Folder: Screening
Form: Visit Date
Generated On: 10 Jun 2021 08:13:30
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:41:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 14:06:01

US3542053
Folder: Screening
Form: Visit Date
Generated On: 10 Jun 2021 08:13:30
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:41:44
User entered '25 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	25 Aug 2020 13:44:33

FDA-CBER-2022-1614-2659951

US3542053
Folder: Screening
Form: Visit Date
Generated On: 10 Jun 2021 08:13:30
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:41:44
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	25 Aug 2020 14:06:01

US3542053
Folder: Screening
Form: Visit Date
Generated On: 10 Jun 2021 08:13:30
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User entered 'SCRN'	System	25 Aug 2020 14:06:01

FDA-CBER-2022-1614-2659953

US3542053
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 08:13:30
Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:41:44
User entered (b) (6) 1961'	RWS_ENDPOINT ENDPOINT (b) (4)	25 Aug 2020 13:44:34

US3542053
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 08:13:30
Age

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:41:44
User entered '59'	(b) (4), (b) (6)	25 Aug 2020 14:06:15

US3542053
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 08:13:30
Age Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User entered 'YEARS'	System	25 Aug 2020 14:06:15

FDA-CBER-2022-1614-2659956

US3542053
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 08:13:30
Age (Derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User entered '59'	System	25 Aug 2020 14:06:30

FDA-CBER-2022-1614-2659957

US3542053
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 08:13:30
Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:41:44
User entered 'Female (F)'	(b) (4), (b) (6)	25 Aug 2020 14:06:15

FDA-CBER-2022-1614-2659958

US3542053
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 08:13:30
Ethnicity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:41:44
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	(b) (4), (b) (6)	25 Aug 2020 14:06:15

US3542053
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 08:13:30
White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:41:44
User entered '1'	(b) (4), (b) (6)	25 Aug 2020 14:06:15

US3542053
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 08:13:30
Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:41:44
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 14:06:15

FDA-CBER-2022-1614-2659961

US3542053
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 08:13:30
Asian

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:41:44
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 14:06:15

US3542053
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 08:13:30
American Indian or Alaska Native

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:41:44
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 14:06:15

FDA-CBER-2022-1614-2659963

US3542053
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 08:13:30
Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:41:44
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 14:06:15

US3542053
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 08:13:30
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:41:44
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 14:06:15

FDA-CBER-2022-1614-2659965

US3542053
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 08:13:30
If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:41:44
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 14:06:15

FDA-CBER-2022-1614-2659966

US3542053
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 08:13:30
Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:41:44
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 14:06:15

FDA-CBER-2022-1614-2659967

US3542053
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 08:13:30
Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:41:44
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 14:06:15

US3542053
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 08:13:30
Date of Informed Consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:41:44
User entered '25 Aug 2020'	(b) (4), (b) (6)	25 Aug 2020 14:06:30

US3542053
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 08:13:30
Month and Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User entered 'Aug 2020'	System	25 Aug 2020 14:06:30

US3542053
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 08:13:30
Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User entered '2020'	System	25 Aug 2020 14:06:30

FDA-CBER-2022-1614-2659971

US3542053
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 08:13:30
Protocol Version

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:41:44
User entered 'Amendment 3 (3)'	(b) (4), (b) (6)	25 Aug 2020 14:06:30

FDA-CBER-2022-1614-2659972

US3542053
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 08:13:30
Was participant enrolled in the study?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:41:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 14:06:30

US3542053
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 08:13:30
If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:41:44
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 14:06:30

FDA-CBER-2022-1614-2659974

US3542053
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 08:13:30
If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:41:44
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 14:06:30

US3542053
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 08:13:30
Was this participant screened previously?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:41:44
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Aug 2020 14:06:50
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Aug 2020 14:06:50
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 14:06:50
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Aug 2020 14:06:30
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 14:06:30

US3542053
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 08:13:30
If Yes, previous participant number

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:41:44
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	25 Aug 2020 13:44:33

FDA-CBER-2022-1614-2659977

US3542053
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 08:13:30
Enrollment Trigger

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User entered '1'	System	25 Aug 2020 14:06:55

FDA-CBER-2022-1614-2659978

US3542053
Folder: Screening
Form: Inclusion/Exclusion Criteria Summary
Generated On: 10 Jun 2021 08:13:30
Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:41:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 14:06:55

US3542053
Folder: Screening
Form: Medical History Summary
Generated On: 10 Jun 2021 08:13:30
Were any significant conditions reported?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:41:44
User entered 'Yes (Y)'	Madhu Balachandran (b) (4)	26 Aug 2020 16:50:26

US3542053
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 08:13:30
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 11:35:27
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' answered with 'this was captured in Med Hx' (Site from DM).	Elissa Malkin (b) (4) (b) (4)	28 Oct 2020 14:38:49
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 10:25:00
User coded data point as SOC: Surgical and medical procedures, HLGT: Cardiac therapeutic procedures, HLT: Cardiac valve therapeutic procedures, PT: Mitral valve replacement, LLT: Mitral valve replacement - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 17:49:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 17:49:35
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:41:44
Data point term sent to Coder	System	26 Aug 2020 16:52:18
User entered 'Mitral Valve Replacement'	Madhu Balachandran (b) (4)	26 Aug 2020 16:51:26

US3542053
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 08:13:30
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:41:44
User entered 'UN UNK 1984'	Madhu Balachandran (b) (4)	26 Aug 2020 16:51:26

US3542053
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 08:13:30
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:41:44
User entered '0'	Madhu Balachandran (b) (4)	26 Aug 2020 16:51:26

US3542053
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 08:13:30
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User signature succeeded.	David Diemert (b) (4) (b) (4)	14 Oct 2020 02:22:54
User closed query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 09:59:07
Query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' answered with 'updated' (Site from DM).	Elissa Malkin (b) (4) (b) (4)	08 Oct 2020 20:00:05
Signature has been broken.	Elissa Malkin (b) (4) (b) (4)	08 Oct 2020 19:59:55
User entered 'No (N)' reason for change: Per Query Resolution	Elissa Malkin (b) (4) (b) (4)	08 Oct 2020 19:59:55
User opened query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 14:04:58
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:41:44
User entered 'Yes (Y)'	Madhu Balachandran (b) (4)	26 Aug 2020 16:51:26

US3542053
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 08:13:30
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User signature succeeded.	David Diemert (b) (4) (b) (4)	09 Mar 2021 04:08:47
Signature has been broken.	David Diemert (b) (4) (b) (4)	03 Mar 2021 20:54:53
User signature succeeded.	David Diemert (b) (4) (b) (4)	14 Oct 2020 02:22:54
Signature has been broken.	Elissa Malkin (b) (4) (b) (4)	08 Oct 2020 19:59:55
User entered 'un UNK 1984' reason for change: Per Query Resolution	Elissa Malkin (b) (4) (b) (4)	08 Oct 2020 19:59:55
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:41:44
User entered empty.	Madhu Balachandran (b) (4)	26 Aug 2020 16:51:26

US3542053
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 08:13:30
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:41:44
User entered '0'	Madhu Balachandran (b) (4)	26 Aug 2020 16:51:26

FDA-CBER-2022-1614-2659986

US3542053
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 08:13:30
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User entered 'Jan 1984'	System	26 Aug 2020 16:51:26

FDA-CBER-2022-1614-2659987

US3542053
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 08:13:30
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User entered '1984'	System	26 Aug 2020 16:51:26

FDA-CBER-2022-1614-2659988

US3542053
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 08:13:30
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User entered 'Jan 1984'	System	08 Oct 2020 19:59:55
User entered empty.	System	26 Aug 2020 16:51:26

FDA-CBER-2022-1614-2659989

US3542053
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 08:13:30
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User entered '1984'	System	08 Oct 2020 19:59:55
User entered empty.	System	26 Aug 2020 16:51:26

FDA-CBER-2022-1614-2659990

US3542053
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 08:13:30
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Arthropathies NEC, PT: Rheumatic fever, LLT: Rheumatic fever - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 17:49:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 17:49:34
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:41:44
Data point term sent to Coder	System	26 Aug 2020 16:52:20
User entered 'Rheumatic Fever'	Madhu Balachandran (b) (4)	26 Aug 2020 16:51:53

FDA-CBER-2022-1614-2659991

US3542053
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 08:13:30
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:41:44
User entered 'UN UNK 1970'	Madhu Balachandran (b) (4)	26 Aug 2020 16:51:53

US3542053
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 08:13:30
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:41:44
User entered '0'	Madhu Balachandran (b) (4)	26 Aug 2020 16:51:53

US3542053
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 08:13:30
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:41:44
User entered 'Yes (Y)'	Madhu Balachandran (b) (4)	26 Aug 2020 16:51:53

FDA-CBER-2022-1614-2659994

US3542053
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 08:13:30
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:41:44
User entered empty.	Madhu Balachandran (b) (4)	26 Aug 2020 16:51:53

US3542053
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 08:13:30
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:41:44
User entered '0'	Madhu Balachandran (b) (4)	26 Aug 2020 16:51:53

US3542053
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 08:13:30
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User entered 'Jan 1970'	System	26 Aug 2020 16:51:53

FDA-CBER-2022-1614-2659997

US3542053
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 08:13:30
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User entered '1970'	System	26 Aug 2020 16:51:53

FDA-CBER-2022-1614-2659998

US3542053
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 08:13:30
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User entered empty.	System	26 Aug 2020 16:51:53

FDA-CBER-2022-1614-2659999

US3542053
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 08:13:30
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User entered empty.	System	26 Aug 2020 16:51:53

US3542053
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 08:13:30
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User signature succeeded.	David Diemert (b) (4) (b) (4)	23 Sep 2020 15:17:42
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal inflammatory conditions, HLT: Gastritis (excl infective), PT: Gastritis, LLT: Gastritis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Sep 2020 18:45:02
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 18:45:02
Data point term sent to Coder	System	22 Sep 2020 18:44:23
User entered 'Gastritis'	Madhu Balachandran (b) (4)	22 Sep 2020 18:43:55

US3542053
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 08:13:30
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:17:42
User entered 'UN Jan 2020'	Madhu Balachandran (b) (4)	22 Sep 2020 18:43:55

FDA-CBER-2022-1614-2660002

US3542053
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 08:13:30
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:17:42
User entered '0'	Madhu Balachandran (b) (4)	22 Sep 2020 18:43:55

FDA-CBER-2022-1614-2660003

US3542053
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 08:13:30
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:17:42
User entered 'Yes (Y)'	Madhu Balachandran (b) (4)	22 Sep 2020 18:43:55

US3542053
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 08:13:30
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User signature succeeded.	David Diemert (b) (4) (b) (4)	23 Sep 2020 15:17:42
User entered empty.	Madhu Balachandran (b) (4)	22 Sep 2020 18:43:55

US3542053
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 08:13:30
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:17:42
User entered '0'	Madhu Balachandran (b) (4)	22 Sep 2020 18:43:55

US3542053
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 08:13:30
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User entered 'Jan 2020'	System	22 Sep 2020 18:43:55

FDA-CBER-2022-1614-2660007

US3542053
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 08:13:30
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User entered '2020'	System	22 Sep 2020 18:43:55

FDA-CBER-2022-1614-2660008

US3542053
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 08:13:30
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User entered empty.	System	22 Sep 2020 18:43:55

FDA-CBER-2022-1614-2660009

US3542053
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 08:13:30
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User entered empty.	System	22 Sep 2020 18:43:55

US3542053
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 08:13:30
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User signature succeeded.	David Diemert (b) (4) (b) (4)	14 Oct 2020 02:22:54
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Menopause, LLT: Menopause - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 16:08:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 16:08:27
Data point term sent to Coder	System	09 Oct 2020 16:07:10
User entered 'Menopause'	Hannah Yellin (b) (4) (b) (4)	09 Oct 2020 16:06:42

US3542053
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 08:13:30
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User signature succeeded.	David Diemert (b) (4) (b) (4)	14 Oct 2020 02:22:54
User entered 'un UNK 2013'	Hannah Yellin (b) (4) (b) (4)	09 Oct 2020 16:06:42

FDA-CBER-2022-1614-2660012

US3542053
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 08:13:30
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User signature succeeded.	David Diemert (b) (4) (b) (4)	14 Oct 2020 02:22:54
User entered '0'	Hannah Yellin (b) (4) (b) (4)	09 Oct 2020 16:06:42

US3542053
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 08:13:30
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User signature succeeded.	David Diemert (b) (4) (b) (4)	14 Oct 2020 02:22:54
User entered 'Yes (Y)'	Hannah Yellin (b) (4) (b) (4)	09 Oct 2020 16:06:42

US3542053
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 08:13:30
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User signature succeeded.	David Diemert (b) (4) (b) (4)	14 Oct 2020 02:22:54
User entered empty.	Hannah Yellin (b) (4) (b) (4)	09 Oct 2020 16:06:42

FDA-CBER-2022-1614-2660015

US3542053
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 08:13:30
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User signature succeeded.	David Diemert (b) (4) (b) (4)	14 Oct 2020 02:22:54
User entered '0'	Hannah Yellin (b) (4) (b) (4)	09 Oct 2020 16:06:42

US3542053
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 08:13:30
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User entered 'Jan 2013'	System	09 Oct 2020 16:06:42

FDA-CBER-2022-1614-2660017

US3542053
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 08:13:30
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User entered '2013'	System	09 Oct 2020 16:06:42

FDA-CBER-2022-1614-2660018

US3542053
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 08:13:30
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User entered empty.	System	09 Oct 2020 16:06:42

FDA-CBER-2022-1614-2660019

US3542053
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 08:13:30
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User entered empty.	System	09 Oct 2020 16:06:42

FDA-CBER-2022-1614-2660020

US3542053
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 08:13:30
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Oct 2020 02:46:06
User coded data point as SOC: Hepatobiliary disorders, HLGT: Gallbladder disorders, HLT: Cholecystitis and cholelithiasis, PT: Cholecystitis, LLT: Cholecystitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 17:33:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 17:33:35
Data point term sent to Coder	System	14 Oct 2020 17:32:48
User entered 'Cholecystitis'	Hannah Yellin (b) (4) (b) (4)	14 Oct 2020 17:32:18

US3542053
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 08:13:30
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User signature succeeded.	David Diemert (b) (4) (b) (4)	09 Mar 2021 04:08:47
User closed query 'Start date is after date of Informed Consent. Please correct.' (Site from System).	System	03 Mar 2021 20:54:13
User entered 'UN Sep 2019' reason for change: Per Query Resolution	David Diemert (b) (4) (b) (4)	03 Mar 2021 20:54:13
User opened query 'Start date is after date of Informed Consent. Please correct.' (Site from System).	System	26 Feb 2021 16:35:57
Signature has been broken.	Erika Faust (b) (4) (b) (4)	26 Feb 2021 16:35:57
User entered 'UN Dec 2020' reason for change: New Information	Erika Faust (b) (4) (b) (4)	26 Feb 2021 16:35:57
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Oct 2020 02:46:06
User entered 'un Sep 2019'	Hannah Yellin (b) (4) (b) (4)	14 Oct 2020 17:32:18

US3542053
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 08:13:30
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Oct 2020 02:46:06
User entered '0'	Hannah Yellin (b) (4) (b) (4)	14 Oct 2020 17:32:18

US3542053
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 08:13:30
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User signature succeeded.	David Diemert (b) (4) (b) (4)	09 Mar 2021 04:08:47
User closed query 'Ongoing is reported as Yes, but Stop Date is provided or Stop date completely unknown is checked. Please correct.' (Site from System).	System	08 Mar 2021 20:56:05
User opened query 'Ongoing is reported as Yes, but Stop Date is provided or Stop date completely unknown is checked. Please correct.' (Site from System).	System	04 Mar 2021 18:02:59
User entered 'Yes (Y)' reason for change: Data Entry Error	Erika Faust (b) (4) (b) (4)	04 Mar 2021 18:02:59
Signature has been broken.	Erika Faust (b) (4) (b) (4)	26 Feb 2021 16:35:57
User entered 'No (N)' reason for change: New Information	Erika Faust (b) (4) (b) (4)	26 Feb 2021 16:35:57
User closed query 'Ongoing is reported as Yes, but Stop Date is provided or Stop date completely unknown is checked. Please correct.' (Site from System).	System	21 Dec 2020 17:21:44
User opened query 'Ongoing is reported as Yes, but Stop Date is provided or Stop date completely unknown is checked. Please correct.' (Site from System).	System	21 Dec 2020 16:00:49
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Oct 2020 02:46:06
User entered 'Yes (Y)'	Hannah Yellin (b) (4) (b) (4)	14 Oct 2020 17:32:18

FDA-CBER-2022-1614-2660024

US3542053
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 08:13:30
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User signature succeeded.	David Diemert (b) (4) (b) (4)	09 Mar 2021 04:08:47
User entered empty; reason for change Per Query Resolution	Elissa Malkin (b) (4) (b) (4)	08 Mar 2021 20:56:05
Signature has been broken.	Erika Faust (b) (4) (b) (4)	26 Feb 2021 16:35:57
User entered 'UN Dec 2020' reason for change: New Information	Erika Faust (b) (4) (b) (4)	26 Feb 2021 16:35:57
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Dec 2020 22:58:26
User entered empty; reason for change Per Query Resolution	Elissa Malkin (b) (4) (b) (4)	21 Dec 2020 17:21:44
Signature has been broken.	Erika Faust (b) (4) (b) (4)	21 Dec 2020 16:00:49
User entered '14 Dec 2020' reason for change: New Information	Erika Faust (b) (4) (b) (4)	21 Dec 2020 16:00:49
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Oct 2020 02:46:06
User entered empty.	Hannah Yellin (b) (4) (b) (4)	14 Oct 2020 17:32:18

FDA-CBER-2022-1614-2660025

US3542053
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 08:13:30
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Oct 2020 02:46:06
User entered '0'	Hannah Yellin (b) (4) (b) (4)	14 Oct 2020 17:32:18

US3542053
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 08:13:30
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User entered 'Sep 2019'	System	03 Mar 2021 20:54:13
User entered 'Dec 2020'	System	26 Feb 2021 16:35:57
User entered 'Sep 2019'	System	14 Oct 2020 17:32:18

US3542053
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 08:13:30
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User entered '2019'	System	03 Mar 2021 20:54:13
User entered '2020'	System	26 Feb 2021 16:35:57
User entered '2019'	System	14 Oct 2020 17:32:18

FDA-CBER-2022-1614-2660028

US3542053
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 08:13:30
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User entered empty.	System	08 Mar 2021 20:56:05
User entered 'Dec 2020'	System	26 Feb 2021 16:35:57
User entered empty.	System	21 Dec 2020 17:21:44
User entered 'Dec 2020'	System	21 Dec 2020 16:00:49
User entered empty.	System	14 Oct 2020 17:32:18

US3542053
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 08:13:30
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User entered empty.	System	08 Mar 2021 20:56:05
User entered '2020'	System	26 Feb 2021 16:35:57
User entered empty.	System	21 Dec 2020 17:21:44
User entered '2020'	System	21 Dec 2020 16:00:49
User entered empty.	System	14 Oct 2020 17:32:18

US3542053
Folder: Screening
Form: Medical History (6)
Generated On: 10 Jun 2021 08:13:30
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User signature succeeded.	David Diemert (b) (4) (b) (4)	12 Feb 2021 19:34:38
User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Transient cerebrovascular events, PT: Transient ischaemic attack, LLT: Transient ischemic attack - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Feb 2021 22:45:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Feb 2021 22:45:39
Data point term sent to Coder	System	10 Feb 2021 22:45:02
User entered 'Transient Ischemic Attack'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:44:33

FDA-CBER-2022-1614-2660031

US3542053
Folder: Screening
Form: Medical History (6)
Generated On: 10 Jun 2021 08:13:30
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User signature succeeded.	David Diemert (b) (4) (b) (4)	12 Feb 2021 19:34:38
User entered empty.	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:44:33

FDA-CBER-2022-1614-2660032

US3542053
Folder: Screening
Form: Medical History (6)
Generated On: 10 Jun 2021 08:13:30
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User signature succeeded.	David Diemert (b) (4) (b) (4)	12 Feb 2021 19:34:38
User entered '1'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:44:33

US3542053
Folder: Screening
Form: Medical History (6)
Generated On: 10 Jun 2021 08:13:30
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User signature succeeded.	David Diemert (b) (4) (b) (4)	12 Feb 2021 19:34:38
User entered 'No (N)'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:44:33

FDA-CBER-2022-1614-2660034

US3542053
Folder: Screening
Form: Medical History (6)
Generated On: 10 Jun 2021 08:13:30
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User signature succeeded.	David Diemert (b) (4) (b) (4)	12 Feb 2021 19:34:38
User entered empty.	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:44:33

FDA-CBER-2022-1614-2660035

US3542053
Folder: Screening
Form: Medical History (6)
Generated On: 10 Jun 2021 08:13:30
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User signature succeeded.	David Diemert (b) (4) (b) (4)	12 Feb 2021 19:34:38
User entered '1'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:44:33

US3542053
Folder: Screening
Form: Medical History (6)
Generated On: 10 Jun 2021 08:13:30
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User entered empty.	System	10 Feb 2021 22:44:33

FDA-CBER-2022-1614-2660037

US3542053
Folder: Screening
Form: Medical History (6)
Generated On: 10 Jun 2021 08:13:30
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User entered empty.	System	10 Feb 2021 22:44:33

FDA-CBER-2022-1614-2660038

US3542053
Folder: Screening
Form: Medical History (6)
Generated On: 10 Jun 2021 08:13:30
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User entered empty.	System	10 Feb 2021 22:44:33

FDA-CBER-2022-1614-2660039

US3542053
Folder: Screening
Form: Medical History (6)
Generated On: 10 Jun 2021 08:13:30
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User entered empty.	System	10 Feb 2021 22:44:33

FDA-CBER-2022-1614-2660040

US3542053
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 08:13:30
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:41:44
User entered 'Yes (Y)'	Madhu Balachandran (b) (4)	26 Aug 2020 16:59:58

FDA-CBER-2022-1614-2660041

US3542053
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 08:13:30
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:41:44
User entered '25 Aug 2020'	Madhu Balachandran (b) (4)	26 Aug 2020 16:59:58

FDA-CBER-2022-1614-2660042

US3542053
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 08:13:30
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:41:44
User entered '09:48'	Madhu Balachandran (b) (4)	26 Aug 2020 16:59:58

FDA-CBER-2022-1614-2660043

US3542053
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 08:13:30
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User entered '25 Aug 2020 09:48'	System	26 Aug 2020 16:59:58

FDA-CBER-2022-1614-2660044

US3542053
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 08:13:30
Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:41:44
User entered '58.5' in	Madhu Balachandran (b) (4)	26 Aug 2020 16:59:58
DataPoint set to visible.	System (b) (4)	25 Aug 2020 14:06:55

FDA-CBER-2022-1614-2660045

US3542053
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 08:13:30
Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:41:44
User entered '120' lb	Madhu Balachandran (b) (4)	26 Aug 2020 16:59:58
DataPoint set to visible.	System (b) (4)	25 Aug 2020 14:06:55

US3542053
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 08:13:30
BMI *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
Amendment Manager: User entered '24.70469'	System	17 Sep 2020 00:22:23
User entered '24.7'	System	26 Aug 2020 16:59:58
DataPoint set to visible.	System	25 Aug 2020 14:06:55

FDA-CBER-2022-1614-2660047

US3542053
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 08:13:30
BMI units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User entered 'kg/m2'	System	26 Aug 2020 16:59:58
DataPoint set to visible.	System	25 Aug 2020 14:06:55

US3542053
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 08:13:30
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:41:44
User entered missing code ND - Not Done.	Madhu Balachandran (b) (4)	26 Aug 2020 16:59:58

US3542053
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 08:13:30
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:41:44
User entered empty.	Madhu Balachandran (b) (4)	26 Aug 2020 16:59:58

US3542053
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 08:13:30
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:41:44
User entered empty.	Madhu Balachandran (b) (4)	26 Aug 2020 16:59:58

US3542053
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 08:13:30
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:41:44
User entered missing code ND - Not Done.	Madhu Balachandran (b) (4)	26 Aug 2020 16:59:58

US3542053
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 08:13:30
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User entered 'bpm'	System	26 Aug 2020 16:59:58

FDA-CBER-2022-1614-2660053

US3542053
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 08:13:30
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:41:44
User entered missing code ND - Not Done.	Madhu Balachandran (b) (4)	26 Aug 2020 16:59:58

US3542053
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 08:13:30
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User entered 'breaths/min'	System	26 Aug 2020 16:59:58

FDA-CBER-2022-1614-2660055

US3542053
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 08:13:30
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:41:44
User entered missing code ND - Not Done.	Madhu Balachandran (b) (4)	26 Aug 2020 16:59:58

FDA-CBER-2022-1614-2660056

US3542053
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 08:13:30
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User entered 'mmHg'	System	26 Aug 2020 16:59:58

FDA-CBER-2022-1614-2660057

US3542053
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 08:13:30
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:41:44
User entered missing code ND - Not Done.	Madhu Balachandran (b) (4)	26 Aug 2020 16:59:58

US3542053
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 08:13:30
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User entered 'mmHg'	System	26 Aug 2020 16:59:58

FDA-CBER-2022-1614-2660059

US3542053
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 08:13:30
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26

FDA-CBER-2022-1614-2660060

US3542053
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 08:13:30
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26

FDA-CBER-2022-1614-2660061

US3542053
Folder: Screening
Form: Physical Examination
Generated On: 10 Jun 2021 08:13:30
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User signature succeeded.	David Diemert (b) (4) (b) (4)	18 Dec 2020 16:14:51
Signature has been broken.	DeEnna Wedding (b) (4) (b) (4)	14 Dec 2020 19:23:55
User entered 'Yes (Y)' reason for change: New Information	DeEnna Wedding (b) (4) (b) (4)	14 Dec 2020 19:23:55
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:41:44
User entered 'No (N)'	Madhu Balachandran (b) (4)	26 Aug 2020 17:00:04

US3542053
Folder: Screening
Form: Physical Examination
Generated On: 10 Jun 2021 08:13:30
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User signature succeeded.	David Diemert (b) (4) (b) (4)	18 Dec 2020 16:14:51
Signature has been broken.	DeEnna Wedding (b) (4) (b) (4)	14 Dec 2020 19:23:55
User entered '25 Aug 2020' reason for change: New Information	DeEnna Wedding (b) (4) (b) (4)	14 Dec 2020 19:23:55
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:41:44
User entered empty.	Madhu Balachandran (b) (4)	26 Aug 2020 17:00:04

US3542053
Folder: Screening
Form: Childbearing Potential
Generated On: 10 Jun 2021 08:13:30
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:41:44
User entered '25 Aug 2020'	Madhu Balachandran (b) (4)	26 Aug 2020 17:01:15

FDA-CBER-2022-1614-2660064

US3542053
Folder: Screening
Form: Childbearing Potential
Generated On: 10 Jun 2021 08:13:30
Is the participant of childbearing potential?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:41:44
User entered 'No (N)'	Madhu Balachandran (b) (4)	26 Aug 2020 17:01:15

US3542053
Folder: Screening
Form: Childbearing Potential
Generated On: 10 Jun 2021 08:13:30
If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User closed query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 09:59:16
Query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' answered with 'Will be added to MH eCRF' (Site from DM).	Elissa Malkin (b) (4) (b) (4)	08 Oct 2020 19:57:52
User opened query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Oct 2020 08:31:29
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:41:44
User closed query 'Is the participant of childbearing potential is No, however reason is missing. Please provide.' (Site from System).	System	26 Aug 2020 17:01:23
User entered 'Post-menopausal (POST-MENOPAUSAL)' reason for change: Data Entry Error	Madhu Balachandran (b) (4)	26 Aug 2020 17:01:23
User opened query 'Is the participant of childbearing potential is No, however reason is missing. Please provide.' (Site from System).	System	26 Aug 2020 17:01:15
User entered empty.	Madhu Balachandran (b) (4)	26 Aug 2020 17:01:15

US3542053
Folder: Screening
Form: Childbearing Potential
Generated On: 10 Jun 2021 08:13:30
If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:41:44
User entered empty.	Madhu Balachandran (b) (4)	26 Aug 2020 17:01:15

FDA-CBER-2022-1614-2660067

US3542053
Folder: Screening
Form: Childbearing Potential
Generated On: 10 Jun 2021 08:13:30
If Surgically sterile, date of surgery *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:41:44
User entered empty.	Madhu Balachandran (b) (4)	26 Aug 2020 17:01:15

FDA-CBER-2022-1614-2660068

US3542053
Folder: Screening
Form: Childbearing Potential
Generated On: 10 Jun 2021 08:13:30
Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:41:44
User entered '0'	Madhu Balachandran (b) (4)	26 Aug 2020 17:01:15

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US3542053
Folder: Screening
Form: Childbearing Potential
Generated On: 10 Jun 2021 08:13:30
If Post-menopausal, date of last menstruation *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:41:44
User entered 'UN UNK 2013'	Madhu Balachandran (b) (4)	26 Aug 2020 17:01:15

US3542053
Folder: Screening
Form: Childbearing Potential
Generated On: 10 Jun 2021 08:13:30
Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:41:44
User entered '0'	Madhu Balachandran (b) (4)	26 Aug 2020 17:01:15

US3542053
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 08:13:30
Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:41:44
User entered 'No (N)'	Madhu Balachandran (b) (4)	26 Aug 2020 17:06:39

US3542053
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 08:13:30
Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:41:44
User entered 'No (N)'	Madhu Balachandran (b) (4)	26 Aug 2020 17:06:39

US3542053
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 08:13:30
Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:41:44
User entered 'No (N)'	Madhu Balachandran (b) (4)	26 Aug 2020 17:06:39

US3542053
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 08:13:30
Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:41:44
User entered 'No (N)'	Madhu Balachandran (b) (4)	26 Aug 2020 17:06:39

US3542053
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 08:13:30
Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:41:44
User entered 'No (N)'	Madhu Balachandran (b) (4)	26 Aug 2020 17:06:39

US3542053
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 08:13:30
Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:41:44
User entered 'No (N)'	Madhu Balachandran (b) (4)	26 Aug 2020 17:06:39

US3542053
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 08:13:30
Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:41:44
User entered 'No (N)'	Madhu Balachandran (b) (4)	26 Aug 2020 17:06:39

US3542053
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 08:13:30
Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:41:44
User entered 'Yes (Y)'	Madhu Balachandran (b) (4)	26 Aug 2020 17:06:39

US3542053
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 08:13:30
Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:41:44
User entered 'No (N)'	Madhu Balachandran (b) (4)	26 Aug 2020 17:06:39

US3542053
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 08:13:30
Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:41:44
User entered 'No (N)'	Madhu Balachandran (b) (4)	26 Aug 2020 17:06:39

US3542053
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 08:13:30
Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:41:44
User entered 'No (N)'	Madhu Balachandran (b) (4)	26 Aug 2020 17:06:39

US3542053
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 08:13:30
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:41:44
User entered 'No (N)'	Madhu Balachandran (b) (4)	26 Aug 2020 17:06:39

US3542053
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 08:13:30
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:41:44
User entered empty.	Madhu Balachandran (b) (4)	26 Aug 2020 17:06:39

US3542053
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 08:13:30
No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:41:44
User entered '0'	Madhu Balachandran (b) (4)	26 Aug 2020 17:06:39

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US3542053
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 08:13:30
Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:41:44
User entered '0'	Madhu Balachandran (b) (4)	26 Aug 2020 17:06:39

US3542053
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 08:13:30
Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:41:44
User entered '1'	Madhu Balachandran (b) (4)	26 Aug 2020 17:06:39

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US3542053
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 08:13:30
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:41:44
User entered '0'	Madhu Balachandran (b) (4)	26 Aug 2020 17:06:39

US3542053
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 08:13:30
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:41:44
User entered '0'	Madhu Balachandran (b) (4)	26 Aug 2020 17:06:39

US3542053
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 08:13:30
Resides in a single family home (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:41:44
User entered '0'	Madhu Balachandran (b) (4)	26 Aug 2020 17:06:39

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US3542053
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 08:13:30
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:41:44
User entered '0'	Madhu Balachandran (b) (4)	26 Aug 2020 17:06:39

FDA-CBER-2022-1614-2660091

US3542053
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 08:13:30
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:26
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:41:44
User entered empty.	Madhu Balachandran (b) (4)	26 Aug 2020 17:06:39

US3542053
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 10 Jun 2021 08:13:30
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:41:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 14:07:16

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US3542053
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 10 Jun 2021 08:13:30
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:41:44
User entered '25 Aug 2020'	(b) (4), (b) (6)	25 Aug 2020 14:07:16

US3542053
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 10 Jun 2021 08:13:30
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:41:44
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	25 Aug 2020 14:07:16

US3542053
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 10 Jun 2021 08:13:30
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User entered 'VISIT1'	System	25 Aug 2020 14:07:16

FDA-CBER-2022-1614-2660096

US3542053
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 08:13:30
What was the date of randomization? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:41:44
User entered '25 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	25 Aug 2020 14:05:18

FDA-CBER-2022-1614-2660097

US3542053
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 08:13:30
What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:41:44
User entered '108119'	RWS_ENDPOINT ENDPOINT (b) (4)	25 Aug 2020 14:05:18

US3542053
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 08:13:30
In what Cohort was the participant enrolled?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:41:44
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	25 Aug 2020 14:05:18

FDA-CBER-2022-1614-2660099

US3542053
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 08:13:30
Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:41:44
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 14:07:26

US3542053
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 08:13:30
Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:41:44
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 14:07:26

US3542053
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 08:13:30
Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:41:44
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 14:07:26

US3542053
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 08:13:30
Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:41:44
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 14:07:26

US3542053
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 08:13:30
Liver Disease

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:41:44
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 14:07:26

US3542053
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 08:13:30
Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:55:32
User entered 'No (N)'	Taylor Ladson (b) (4)	06 Oct 2020 14:05:07
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 02:48:41
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 02:48:40

US3542053
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 08:13:30
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:41:44
User entered missing code ND - Not Done; reason for change Data Entry Error	Madhu Balachandran (b) (4)	26 Aug 2020 17:09:23
User entered missing code ND - Not Done; reason for change Data Entry Error	Madhu Balachandran (b) (4)	26 Aug 2020 17:08:46
User entered '58.5' in	(b) (4), (b) (6)	25 Aug 2020 14:07:46

US3542053
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 08:13:30
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:41:44
User entered missing code ND - Not Done; reason for change Data Entry Error	Madhu Balachandran (b) (4)	26 Aug 2020 17:09:23
User entered missing code ND - Not Done; reason for change Data Entry Error	Madhu Balachandran (b) (4)	26 Aug 2020 17:08:46
User entered '120' lb	(b) (4), (b) (6)	25 Aug 2020 14:07:46

US3542053
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 08:13:30
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:41:44
User entered missing code ND - Not Done; reason for change Data Entry Error	Madhu Balachandran (b) (4)	26 Aug 2020 17:09:23
User entered missing code ND - Not Done; reason for change Data Entry Error	Madhu Balachandran (b) (4)	26 Aug 2020 17:08:46
User entered '58.5' in	(b) (4), (b) (6)	25 Aug 2020 14:07:46

US3542053
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 08:13:30
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:41:44
User entered missing code ND - Not Done; reason for change Data Entry Error	Madhu Balachandran (b) (4)	26 Aug 2020 17:09:23
User entered missing code ND - Not Done; reason for change Data Entry Error	Madhu Balachandran (b) (4)	26 Aug 2020 17:08:46
User entered '120' lb	(b) (4), (b) (6)	25 Aug 2020 14:07:46

US3542053
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 08:13:30
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	25 Aug 2020 14:07:46

US3542053
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 08:13:30
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:41:44
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Aug 2020 17:08:46
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Aug 2020 17:08:46
User entered 'Yes (Y)' reason for change: Data Entry Error	Madhu Balachandran (b) (4)	26 Aug 2020 17:08:46
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Aug 2020 14:07:46
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 14:07:46

US3542053
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 08:13:30
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:41:44
User entered '25 Aug 2020' reason for change: Data Entry Error	Madhu Balachandran (b) (4)	26 Aug 2020 17:08:46
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 14:07:46

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US3542053
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 08:13:30
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:41:44
User entered '09:48' reason for change: Data Entry Error	(b) (4) Madhu Balachandran	26 Aug 2020 17:08:46
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 14:07:46

US3542053
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 08:13:30
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User entered '25 Aug 2020 09:48'	System	26 Aug 2020 17:08:46
User entered empty.	System	25 Aug 2020 14:07:46

US3542053
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 08:13:30
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:41:44
User entered '97.9' F reason for change: Data Entry Error	(b) (4) Madhu Balachandran	26 Aug 2020 17:08:46
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 14:07:46

US3542053
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 08:13:30
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:41:44
User entered 'Oral (Oral)' reason for change: Data Entry Error	Madhu Balachandran (b) (4)	26 Aug 2020 17:08:46
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 14:07:46

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US3542053
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 08:13:30
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:41:44
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 14:07:46

US3542053
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 08:13:30
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:41:44
User entered '72' reason for change: Data Entry Error	Madhu Balachandran (b) (4)	26 Aug 2020 17:08:46
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 14:07:46

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US3542053
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 08:13:30
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User entered 'bpm'	System	26 Aug 2020 17:08:46
User entered empty.	System	25 Aug 2020 14:07:46

FDA-CBER-2022-1614-2660119

US3542053
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 08:13:30
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:41:44
User entered '12' reason for change: Data Entry Error	Madhu Balachandran (b) (4)	26 Aug 2020 17:08:46
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 14:07:46

FDA-CBER-2022-1614-2660120

US3542053
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 08:13:30
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User entered 'breaths/min'	System	26 Aug 2020 17:08:46
User entered empty.	System	25 Aug 2020 14:07:46

US3542053
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 08:13:30
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:41:44
User entered '134' reason for change: Data Entry Error	(b) (4) Madhu Balachandran	26 Aug 2020 17:08:46
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 14:07:46

FDA-CBER-2022-1614-2660122

US3542053
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 08:13:30
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User entered 'mmHg'	System	26 Aug 2020 17:08:46
User entered empty.	System	25 Aug 2020 14:07:46

US3542053
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 08:13:30
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:41:44
User entered '79' reason for change: Data Entry Error	Madhu Balachandran (b) (4)	26 Aug 2020 17:08:46
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 14:07:46

FDA-CBER-2022-1614-2660124

US3542053
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 08:13:30
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User entered 'mmHg'	System	26 Aug 2020 17:08:46
User entered empty.	System	25 Aug 2020 14:07:46

US3542053
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 08:13:30
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:41:44
User entered missing code ND - Not Done; reason for change Data Entry Error	Madhu Balachandran (b) (4)	26 Aug 2020 17:09:23
User entered missing code ND - Not Done; reason for change Data Entry Error	Madhu Balachandran (b) (4)	26 Aug 2020 17:08:46
User entered '58.5' in	(b) (4), (b) (6)	25 Aug 2020 14:07:46

US3542053
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 08:13:30
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:41:44
User entered missing code ND - Not Done; reason for change Data Entry Error	Madhu Balachandran (b) (4)	26 Aug 2020 17:09:23
User entered missing code ND - Not Done; reason for change Data Entry Error	Madhu Balachandran (b) (4)	26 Aug 2020 17:08:46
User entered '120' lb	(b) (4), (b) (6)	25 Aug 2020 14:07:46

US3542053
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 08:13:30
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	25 Aug 2020 14:07:46

FDA-CBER-2022-1614-2660128

US3542053
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 08:13:30
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:41:44
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Aug 2020 17:08:46
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Aug 2020 17:08:46
User entered 'Yes (Y)' reason for change: Data Entry Error	Madhu Balachandran (b) (4)	26 Aug 2020 17:08:46
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Aug 2020 14:07:46
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 14:07:46

US3542053
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 08:13:30
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:41:44
User entered '25 Aug 2020' reason for change: Data Entry Error	Madhu Balachandran (b) (4)	26 Aug 2020 17:08:46
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 14:07:46

FDA-CBER-2022-1614-2660130

US3542053
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 08:13:30
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:41:44
User entered '11:32' reason for change: Data Entry Error	(b) (4) Madhu Balachandran	26 Aug 2020 17:08:46
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 14:07:46

US3542053
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 08:13:30
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User entered '25 Aug 2020 11:32'	System	26 Aug 2020 17:08:46
User entered empty.	System	25 Aug 2020 14:07:46

US3542053
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 08:13:30
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:41:44
User entered '98.0' F reason for change: Data Entry Error	(b) (4) Madhu Balachandran	26 Aug 2020 17:08:46
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 14:07:46

US3542053
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 08:13:30
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:41:44
User entered 'Oral (Oral)' reason for change: Data Entry Error	Madhu Balachandran (b) (4)	26 Aug 2020 17:08:46
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 14:07:46

FDA-CBER-2022-1614-2660134

US3542053
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 08:13:30
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:41:44
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 14:07:46

US3542053
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 08:13:30
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:41:44
User entered '65' reason for change: Data Entry Error	Madhu Balachandran (b) (4)	26 Aug 2020 17:08:46
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 14:07:46

US3542053
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 08:13:30
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User entered 'bpm'	System	26 Aug 2020 17:08:46
User entered empty.	System	25 Aug 2020 14:07:46

FDA-CBER-2022-1614-2660137

US3542053
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 08:13:30
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:41:44
User entered '14' reason for change: Data Entry Error	(b) (4) Madhu Balachandran	26 Aug 2020 17:08:46
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 14:07:46

FDA-CBER-2022-1614-2660138

US3542053
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 08:13:30
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User entered 'breaths/min'	System	26 Aug 2020 17:08:46
User entered empty.	System	25 Aug 2020 14:07:46

US3542053
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 08:13:30
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:41:44
User entered '126' reason for change: Data Entry Error	Madhu Balachandran (b) (4)	26 Aug 2020 17:08:46
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 14:07:46

FDA-CBER-2022-1614-2660140

US3542053
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 08:13:30
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User entered 'mmHg'	System	26 Aug 2020 17:08:46
User entered empty.	System	25 Aug 2020 14:07:46

FDA-CBER-2022-1614-2660141

US3542053
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 08:13:30
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:41:44
User entered '69' reason for change: Data Entry Error	(b) (4) Madhu Balachandran	26 Aug 2020 17:08:46
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 14:07:46

FDA-CBER-2022-1614-2660142

US3542053
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 08:13:30
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User entered 'mmHg'	System	26 Aug 2020 17:08:46
User entered empty.	System	25 Aug 2020 14:07:46

US3542053
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 10 Jun 2021 08:13:30
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	18 Dec 2020 16:14:51
Signature has been broken.	DeEnna Wedding (b) (4) (b) (4)	14 Dec 2020 19:24:14
User entered 'No (N)' reason for change: New Information	DeEnna Wedding (b) (4) (b) (4)	14 Dec 2020 19:24:14
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:41:44
User entered 'Yes (Y)'	Madhu Balachandran (b) (4)	26 Aug 2020 17:10:01

US3542053
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 10 Jun 2021 08:13:30
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	18 Dec 2020 16:14:51
Signature has been broken.	DeEnna Wedding (b) (4) (b) (4)	14 Dec 2020 19:24:14
User entered empty; reason for change New Information	DeEnna Wedding (b) (4) (b) (4)	14 Dec 2020 19:24:14
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:41:44
User entered '25 Aug 2020'	Madhu Balachandran (b) (4)	26 Aug 2020 17:10:01

US3542053
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 08:13:30
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:41:44
User entered 'Yes (Y)'	Elissa Malkin (b) (4) (b) (4)	25 Aug 2020 15:29:29

US3542053
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 08:13:30
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:41:44
User entered empty.	Elissa Malkin (b) (4) (b) (4)	25 Aug 2020 15:29:29

FDA-CBER-2022-1614-2660147

US3542053
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 08:13:30
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:41:44
User entered empty.	Elissa Malkin (b) (4) (b) (4)	25 Aug 2020 15:29:29

US3542053
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 08:13:30
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User entered 'MRNA-1273 OR PLACEBO'	System	25 Aug 2020 15:29:29

US3542053
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 08:13:30
What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:41:44
User entered '25 Aug 2020'	Elissa Malkin (b) (4) (b) (4)	25 Aug 2020 15:29:29

US3542053
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 08:13:30
What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:41:44
User entered '10:59'	Elissa Malkin (b) (4) (b) (4)	25 Aug 2020 15:29:29

US3542053
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 08:13:30
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User entered '25 Aug 2020 10:59'	System	25 Aug 2020 15:29:29

FDA-CBER-2022-1614-2660152

US3542053
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 08:13:30
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:41:44
User entered 'Left Arm (LEFT ARM)'	Elissa Malkin (b) (4) (b) (4)	25 Aug 2020 15:29:29

US3542053
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 08:13:30
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User entered 'ONCE'	System	25 Aug 2020 15:29:29

FDA-CBER-2022-1614-2660154

US3542053
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 08:13:30
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User entered 'INTRAMUSCULAR'	System	25 Aug 2020 15:29:29

US3542053
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 08:13:30
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:41:44
User entered 'Yes (Y)'	(b) (4) Madhu Balachandran (b) (4)	26 Aug 2020 17:10:21

US3542053
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 08:13:30
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 25AUG2020 is recorded under Visit 1 Day 1 visit in EDC, however the same is reported under Visit 1 Day 1 Visit with date 24AUG2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 12:01:02
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 25AUG2020 is recorded under Visit 1 Day 1 visit in EDC, however the same is reported under Visit 1 Day 1 Visit with date 24AUG2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' answered with 'The correct date is 25Aug20. A request was already submitted by site processing lab to fix the date.' (Site from DM).	Hannah Yellin (b) (4) (b) (4)	11 Nov 2020 16:32:23
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 25AUG2020 is recorded under Visit 1 Day 1 visit in EDC, however the same is reported under Visit 1 Day 1 Visit with date 24AUG2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 14:49:07
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:41:44
User entered '25 Aug 2020'	Madhu Balachandran (b) (4)	26 Aug 2020 17:10:21

US3542053
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 08:13:30
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:41:44
User entered '10:19'	Madhu Balachandran (b) (4)	26 Aug 2020 17:10:21

FDA-CBER-2022-1614-2660158

US3542053
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 08:13:30
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User entered '25 Aug 2020 10:19'	System	26 Aug 2020 17:10:21

FDA-CBER-2022-1614-2660159

US3542053
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab
Generated On: 10 Jun 2021 08:13:30
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User closed query 'Per GCL Lab Reconciliation: Swab: Collection date in EDC is 25Aug2020 for Visit 1 Day 1 visit, however in GCL collection date entered is 24Aug2020 for the same visit. Please confirm if the collection date 25Aug2020 is correct to update in GCL records. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 10:03:31
Query 'Per GCL Lab Reconciliation: Swab: Collection date in EDC is 25Aug2020 for Visit 1 Day 1 visit, however in GCL collection date entered is 24Aug2020 for the same visit. Please confirm if the collection date 25Aug2020 is correct to update in GCL records. ' answered with 'Collection date 25Aug20 is correct. ' (Site from DM).	Hannah Yellin (b) (4) (b) (4)	23 Oct 2020 17:12:46
User opened query 'Per GCL Lab Reconciliation: Swab: Collection date in EDC is 25Aug2020 for Visit 1 Day 1 visit, however in GCL collection date entered is 24Aug2020 for the same visit. Please confirm if the collection date 25Aug2020 is correct to update in GCL records. ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 05:37:37
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:41:44
User entered '25 Aug 2020'	Madhu Balachandran (b) (4)	26 Aug 2020 17:10:31

FDA-CBER-2022-1614-2660160

US3542053
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 08:13:30
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Madhu Balachandran (b) (4)	26 Aug 2020 17:10:31

US3542053
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 08:13:30
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:41:44
User entered 'Yes (Y)'	Madhu Balachandran (b) (4)	26 Aug 2020 17:10:31

US3542053
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 08:13:30
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:41:44
User entered '10:20'	Madhu Balachandran (b) (4)	26 Aug 2020 17:10:31

US3542053
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 08:13:30
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User entered '25 Aug 2020 10:20'	System	26 Aug 2020 17:10:31

FDA-CBER-2022-1614-2660164

US3542053
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 08:13:30
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Madhu Balachandran (b) (4)	26 Aug 2020 17:10:31

US3542053
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 08:13:30
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:41:44
User entered 'No (N)'	Madhu Balachandran (b) (4)	26 Aug 2020 17:10:31

US3542053
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 08:13:30
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:41:44
User entered empty.	(b) (4) Madhu Balachandran (b) (4)	26 Aug 2020 17:10:31

US3542053
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 08:13:30
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User entered empty.	System	26 Aug 2020 17:10:31

FDA-CBER-2022-1614-2660168

US3542053
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 10 Jun 2021 08:13:30
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:41:44
User entered 'Yes (Y)'	Madhu Balachandran (b) (4)	26 Aug 2020 17:10:43

US3542053
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 10 Jun 2021 08:13:30
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User entered '1'	System	26 Aug 2020 17:10:43

FDA-CBER-2022-1614-2660170

US3542053
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
Data entry locked.	System	25 Aug 2020 15:29:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Aug 2020 15:29:29

FDA-CBER-2022-1614-2660171

US3542053
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 08:13:30
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-25T11:33:44', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '9c7e5992-0cf1-4226-95ae-9e9857426129'	System	25 Aug 2020 15:34:14
User entered 'Yes (Y)'	System	25 Aug 2020 15:34:14

FDA-CBER-2022-1614-2660172

US3542053
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 08:13:30
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-25T11:33:58', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '9c7e5992-0cf1-4226-95ae-9e9857426129'	System	25 Aug 2020 15:34:14
User entered '98.0'	System	25 Aug 2020 15:34:14

FDA-CBER-2022-1614-2660173

US3542053
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 08:13:30
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-25T11:34:03', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '9c7e5992-0cf1-4226-95ae-9e9857426129'	System	25 Aug 2020 15:34:14
User entered 'No (N)'	System	25 Aug 2020 15:34:14

FDA-CBER-2022-1614-2660174

US3542053
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 08:13:30
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-25T11:34:11', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '9c7e5992-0cf1-4226-95ae-9e9857426129'	System	25 Aug 2020 15:34:14
User entered '25 Aug 2020 11:34'	System	25 Aug 2020 15:34:14

FDA-CBER-2022-1614-2660175

US3542053
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 08:13:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '25 Aug 2020 11:19'	System	25 Aug 2020 15:29:29

FDA-CBER-2022-1614-2660176

US3542053
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 08:13:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '25 Aug 2020 13:49'	System	25 Aug 2020 15:29:29

FDA-CBER-2022-1614-2660177

US3542053
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
Data entry locked.	System	25 Aug 2020 15:29:29
User entered 'Day 1, after vaccination (at home)'	System	25 Aug 2020 15:29:29

FDA-CBER-2022-1614-2660178

US3542053
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 08:13:30
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-25T21:59:47', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '559a9aa9-516d-4d38-af06-f8cde717e829'	System	26 Aug 2020 02:00:43
User entered 'Yes (Y)'	System	26 Aug 2020 02:00:43

FDA-CBER-2022-1614-2660179

US3542053
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 08:13:30
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-25T22:00:07', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '559a9aa9-516d-4d38-af06-f8cde717e829'	System	26 Aug 2020 02:00:43
User entered '97.2'	System	26 Aug 2020 02:00:43

US3542053
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 08:13:30
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-25T22:00:33', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '559a9aa9-516d-4d38-af06-f8cde717e829'	System	26 Aug 2020 02:00:43
User entered 'No (N)'	System	26 Aug 2020 02:00:43

FDA-CBER-2022-1614-2660181

US3542053
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 08:13:30
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-25T22:00:39', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '559a9aa9-516d-4d38-af06-f8cde717e829'	System	26 Aug 2020 02:00:43
User entered '25 Aug 2020 22:00'	System	26 Aug 2020 02:00:43

FDA-CBER-2022-1614-2660182

US3542053
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 08:13:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '25 Aug 2020 14:44'	System	25 Aug 2020 15:29:29

FDA-CBER-2022-1614-2660183

US3542053
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 08:13:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '26 Aug 2020 11:59'	System	25 Aug 2020 15:29:29

FDA-CBER-2022-1614-2660184

US3542053
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
Data entry locked.	System	25 Aug 2020 15:29:29
User entered 'Day 2'	System	25 Aug 2020 15:29:29

US3542053
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 08:13:30
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-26T21:57:14', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'a5f93d8e-c45c-492c-9a59-094b8586a858'	System	27 Aug 2020 01:57:40
User entered 'Yes (Y)'	System	27 Aug 2020 01:57:40

FDA-CBER-2022-1614-2660186

US3542053
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 08:13:30
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-26T21:57:24', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'a5f93d8e-c45c-492c-9a59-094b8586a858'	System	27 Aug 2020 01:57:40
User entered '97.1'	System	27 Aug 2020 01:57:40

FDA-CBER-2022-1614-2660187

US3542053
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 08:13:30
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-26T21:57:29', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'a5f93d8e-c45c-492c-9a59-094b8586a858'	System	27 Aug 2020 01:57:40
User entered 'No (N)'	System	27 Aug 2020 01:57:40

FDA-CBER-2022-1614-2660188

US3542053
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 08:13:30
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-26T21:57:38', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'a5f93d8e-c45c-492c-9a59-094b8586a858'	System	27 Aug 2020 01:57:40
User entered '26 Aug 2020 21:57'	System	27 Aug 2020 01:57:40

US3542053
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 08:13:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '26 Aug 2020 12:00'	System	25 Aug 2020 15:29:29

FDA-CBER-2022-1614-2660190

US3542053
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 08:13:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '27 Aug 2020 11:59'	System	25 Aug 2020 15:29:29

FDA-CBER-2022-1614-2660191

US3542053
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
Data entry locked.	System	25 Aug 2020 15:29:29
User entered 'Day 3'	System	25 Aug 2020 15:29:29

FDA-CBER-2022-1614-2660192

US3542053
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 08:13:30
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-27T22:05:15', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'cf028f90-272d-4c99-844f-58dec1f071a2'	System	28 Aug 2020 02:05:41
User entered 'Yes (Y)'	System	28 Aug 2020 02:05:41

FDA-CBER-2022-1614-2660193

US3542053
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 08:13:30
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-27T22:05:21', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'cf028f90-272d-4c99-844f-58dec1f071a2'	System	28 Aug 2020 02:05:41
User entered '98.0'	System	28 Aug 2020 02:05:41

FDA-CBER-2022-1614-2660194

US3542053
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 08:13:30
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-27T22:05:26', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'cf028f90-272d-4c99-844f-58dec1f071a2'	System	28 Aug 2020 02:05:41
User entered 'No (N)'	System	28 Aug 2020 02:05:41

FDA-CBER-2022-1614-2660195

US3542053
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 08:13:30
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-27T22:05:37', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'cf028f90-272d-4c99-844f-58dec1f071a2'	System	28 Aug 2020 02:05:41
User entered '27 Aug 2020 22:05'	System	28 Aug 2020 02:05:41

US3542053
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 08:13:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '27 Aug 2020 12:00'	System	25 Aug 2020 15:29:29

FDA-CBER-2022-1614-2660197

US3542053
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 08:13:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '28 Aug 2020 11:59'	System	25 Aug 2020 15:29:29

FDA-CBER-2022-1614-2660198

US3542053
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
Data entry locked.	System	25 Aug 2020 15:29:29
User entered 'Day 4'	System	25 Aug 2020 15:29:29

US3542053
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 08:13:30
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-28T22:32:31', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'daf0c078-6545-4aa8-94fa-7b4eb6974a05'	System	29 Aug 2020 02:32:52
User entered 'Yes (Y)'	System	29 Aug 2020 02:32:52

FDA-CBER-2022-1614-2660200

US3542053
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 08:13:30
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-28T22:32:37', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'daf0c078-6545-4aa8-94fa-7b4eb6974a05'	System	29 Aug 2020 02:32:52
User entered '97.4'	System	29 Aug 2020 02:32:52

FDA-CBER-2022-1614-2660201

US3542053
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 08:13:30
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-28T22:32:41', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'daf0c078-6545-4aa8-94fa-7b4eb6974a05'	System	29 Aug 2020 02:32:52
User entered 'No (N)'	System	29 Aug 2020 02:32:52

FDA-CBER-2022-1614-2660202

US3542053
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 08:13:30
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-28T22:32:47', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'daf0c078-6545-4aa8-94fa-7b4eb6974a05'	System	29 Aug 2020 02:32:52
User entered '28 Aug 2020 22:32'	System	29 Aug 2020 02:32:52

FDA-CBER-2022-1614-2660203

US3542053
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 08:13:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '28 Aug 2020 12:00'	System	25 Aug 2020 15:29:29

FDA-CBER-2022-1614-2660204

US3542053
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 08:13:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '29 Aug 2020 11:59'	System	25 Aug 2020 15:29:29

FDA-CBER-2022-1614-2660205

US3542053
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
Data entry locked.	System	25 Aug 2020 15:29:29
User entered 'Day 5'	System	25 Aug 2020 15:29:29

FDA-CBER-2022-1614-2660206

US3542053
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 08:13:30
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-30T00:05:35', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '47995ab0-24c6-431b-8e63-254046700f42'	System	30 Aug 2020 04:05:53
User entered 'Yes (Y)'	System	30 Aug 2020 04:05:53

FDA-CBER-2022-1614-2660207

US3542053
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 08:13:30
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-30T00:05:43', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '47995ab0-24c6-431b-8e63-254046700f42'	System	30 Aug 2020 04:05:53
User entered '96.7'	System	30 Aug 2020 04:05:53

US3542053
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 08:13:30
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-30T00:05:47', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '47995ab0-24c6-431b-8e63-254046700f42'	System	30 Aug 2020 04:05:53
User entered 'No (N)'	System	30 Aug 2020 04:05:53

FDA-CBER-2022-1614-2660209

US3542053
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 08:13:30
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-30T00:05:51', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '47995ab0-24c6-431b-8e63-254046700f42'	System	30 Aug 2020 04:05:53
User entered '30 Aug 2020 00:05'	System	30 Aug 2020 04:05:53

FDA-CBER-2022-1614-2660210

US3542053
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 08:13:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '29 Aug 2020 12:00'	System	25 Aug 2020 15:29:29

FDA-CBER-2022-1614-2660211

US3542053
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 08:13:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '30 Aug 2020 11:59'	System	25 Aug 2020 15:29:29

FDA-CBER-2022-1614-2660212

US3542053
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
Data entry locked.	System	25 Aug 2020 15:29:29
User entered 'Day 6'	System	25 Aug 2020 15:29:29

FDA-CBER-2022-1614-2660213

US3542053
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 08:13:30
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-30T22:01:43', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '948d9dff-727c-47d5-af4c-2f6cb162f953'	System	31 Aug 2020 02:02:00
User entered 'Yes (Y)'	System	31 Aug 2020 02:02:00

FDA-CBER-2022-1614-2660214

US3542053
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 08:13:30
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-30T22:01:48', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '948d9dff-727c-47d5-af4c-2f6cb162f953'	System	31 Aug 2020 02:02:00
User entered '99.4'	System	31 Aug 2020 02:02:00

FDA-CBER-2022-1614-2660215

US3542053
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 08:13:30
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-30T22:01:52', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '948d9dff-727c-47d5-af4c-2f6cb162f953'	System	31 Aug 2020 02:02:00
User entered 'No (N)'	System	31 Aug 2020 02:02:00

FDA-CBER-2022-1614-2660216

US3542053
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 08:13:30
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-30T22:01:58', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '948d9dff-727c-47d5-af4c-2f6cb162f953'	System	31 Aug 2020 02:02:00
User entered '30 Aug 2020 22:01'	System	31 Aug 2020 02:02:00

FDA-CBER-2022-1614-2660217

US3542053
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 08:13:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '30 Aug 2020 12:00'	System	25 Aug 2020 15:29:29

FDA-CBER-2022-1614-2660218

US3542053
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 08:13:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '31 Aug 2020 11:59'	System	25 Aug 2020 15:29:29

FDA-CBER-2022-1614-2660219

US3542053
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
Data entry locked.	System	25 Aug 2020 15:29:29
User entered 'Day 7'	System	25 Aug 2020 15:29:29

FDA-CBER-2022-1614-2660220

US3542053
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 08:13:30
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-31T22:56:19', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'a1c8a21c-b99a-4ec5-ba80-5b2a2b3642ac'	System	01 Sep 2020 02:56:41
User entered 'Yes (Y)'	System	01 Sep 2020 02:56:41

FDA-CBER-2022-1614-2660221

US3542053
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 08:13:30
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-31T22:56:26', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'a1c8a21c-b99a-4ec5-ba80-5b2a2b3642ac'	System	01 Sep 2020 02:56:41
User entered '97.4'	System	01 Sep 2020 02:56:41

FDA-CBER-2022-1614-2660222

US3542053
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 08:13:30
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-31T22:56:30', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'a1c8a21c-b99a-4ec5-ba80-5b2a2b3642ac'	System	01 Sep 2020 02:56:41
User entered 'No (N)'	System	01 Sep 2020 02:56:41

FDA-CBER-2022-1614-2660223

US3542053
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 08:13:30
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-31T22:56:39', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'a1c8a21c-b99a-4ec5-ba80-5b2a2b3642ac'	System	01 Sep 2020 02:56:41
User entered '31 Aug 2020 22:56'	System	01 Sep 2020 02:56:41

US3542053
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 08:13:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '31 Aug 2020 12:00'	System	25 Aug 2020 15:29:29

FDA-CBER-2022-1614-2660225

US3542053
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 08:13:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '01 Sep 2020 11:59'	System	25 Aug 2020 15:29:29

FDA-CBER-2022-1614-2660226

US3542053
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
Data entry locked.	System	25 Aug 2020 15:29:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Aug 2020 15:29:29

FDA-CBER-2022-1614-2660227

US3542053
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 08:13:30
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 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-25T11:34:25', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'c0784c43-3c60-4875-af15-df8cfc8847df'	System	26 Aug 2020 01:07:18
User entered 'None (1)'	System	26 Aug 2020 01:07:18

FDA-CBER-2022-1614-2660228

US3542053
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 08:13:30
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-25T11:34:36', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'c0784c43-3c60-4875-af15-df8cfc8847df'	System	26 Aug 2020 01:07:18
User entered 'No (N)'	System	26 Aug 2020 01:07:18

FDA-CBER-2022-1614-2660229

US3542053
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 08:13:30
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-25T11:34:39', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'c0784c43-3c60-4875-af15-df8cfc8847df'	System	26 Aug 2020 01:07:18
User entered 'No (N)'	System	26 Aug 2020 01:07:18

FDA-CBER-2022-1614-2660230

US3542053
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 08:13:30
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 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-25T11:34:43', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'c0784c43-3c60-4875-af15-df8cfc8847df'	System	26 Aug 2020 01:07:18
User entered 'None (1)'	System	26 Aug 2020 01:07:18

US3542053
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 08:13:30
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-25T11:34:47', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'c0784c43-3c60-4875-af15-df8cfc8847df'	System	26 Aug 2020 01:07:18
User entered '25 Aug 2020 11:34'	System	26 Aug 2020 01:07:18

FDA-CBER-2022-1614-2660232

US3542053
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 08:13:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '25 Aug 2020 11:19'	System	25 Aug 2020 15:29:29

FDA-CBER-2022-1614-2660233

US3542053
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 08:13:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '25 Aug 2020 13:49'	System	25 Aug 2020 15:29:29

FDA-CBER-2022-1614-2660234

US3542053
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
Data entry locked.	System	25 Aug 2020 15:29:29
User entered 'Day 1, after vaccination (at home)'	System	25 Aug 2020 15:29:29

US3542053
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 08:13:30
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 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-25T22:01:01', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'efef45aa-fd30-4df1-b03d-d3552c38b825'	System	26 Aug 2020 02:01:26
User entered 'None (1)'	System	26 Aug 2020 02:01:26

FDA-CBER-2022-1614-2660236

US3542053
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 08:13:30
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-25T22:01:05', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'efef45aa-fd30-4df1-b03d-d3552c38b825'	System	26 Aug 2020 02:01:26
User entered 'No (N)'	System	26 Aug 2020 02:01:26

FDA-CBER-2022-1614-2660237

US3542053
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 08:13:30
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-25T22:01:08', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'efef45aa-fd30-4df1-b03d-d3552c38b825'	System	26 Aug 2020 02:01:26
User entered 'No (N)'	System	26 Aug 2020 02:01:26

FDA-CBER-2022-1614-2660238

US3542053
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 08:13:30
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 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-25T22:01:13', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'efef45aa-fd30-4df1-b03d-d3552c38b825'	System	26 Aug 2020 02:01:26
User entered 'None (1)'	System	26 Aug 2020 02:01:26

FDA-CBER-2022-1614-2660239

US3542053
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 08:13:30
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-25T22:01:24', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'efef45aa-fd30-4df1-b03d-d3552c38b825'	System	26 Aug 2020 02:01:26
User entered '25 Aug 2020 22:01'	System	26 Aug 2020 02:01:26

FDA-CBER-2022-1614-2660240

US3542053
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 08:13:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '25 Aug 2020 14:44'	System	25 Aug 2020 15:29:29

FDA-CBER-2022-1614-2660241

US3542053
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 08:13:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '26 Aug 2020 11:59'	System	25 Aug 2020 15:29:29

FDA-CBER-2022-1614-2660242

US3542053
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
Data entry locked.	System	25 Aug 2020 15:29:29
User entered 'Day 2'	System	25 Aug 2020 15:29:29

FDA-CBER-2022-1614-2660243

US3542053
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 08:13:30
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 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-26T21:57:56', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '84c02c96-2a78-4cda-9335-b4ad28a88ca7'	System	27 Aug 2020 01:58:18
User entered 'None (1)'	System	27 Aug 2020 01:58:18

FDA-CBER-2022-1614-2660244

US3542053
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 08:13:30
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-26T21:58:01', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '84c02c96-2a78-4cda-9335-b4ad28a88ca7'	System	27 Aug 2020 01:58:18
User entered 'No (N)'	System	27 Aug 2020 01:58:18

US3542053
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 08:13:30
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-26T21:58:04', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '84c02c96-2a78-4cda-9335-b4ad28a88ca7'	System	27 Aug 2020 01:58:18
User entered 'No (N)'	System	27 Aug 2020 01:58:18

US3542053
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 08:13:30
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 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-26T21:58:09', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '84c02c96-2a78-4cda-9335-b4ad28a88ca7'	System	27 Aug 2020 01:58:18
User entered 'None (1)'	System	27 Aug 2020 01:58:18

FDA-CBER-2022-1614-2660247

US3542053
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 08:13:30
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-26T21:58:16', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '84c02c96-2a78-4cda-9335-b4ad28a88ca7'	System	27 Aug 2020 01:58:18
User entered '26 Aug 2020 21:58'	System	27 Aug 2020 01:58:18

FDA-CBER-2022-1614-2660248

US3542053
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 08:13:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '26 Aug 2020 12:00'	System	25 Aug 2020 15:29:29

FDA-CBER-2022-1614-2660249

US3542053
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 08:13:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '27 Aug 2020 11:59'	System	25 Aug 2020 15:29:29

FDA-CBER-2022-1614-2660250

US3542053
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
Data entry locked.	System	25 Aug 2020 15:29:29
User entered 'Day 3'	System	25 Aug 2020 15:29:29

FDA-CBER-2022-1614-2660251

US3542053
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 08:13:30
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 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-27T22:05:43', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '2debea64-f244-4391-8fc7-49ad56d0ea3e'	System	28 Aug 2020 02:06:04
User entered 'None (1)'	System	28 Aug 2020 02:06:04

FDA-CBER-2022-1614-2660252

US3542053
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 08:13:30
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-27T22:05:48', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '2debea64-f244-4391-8fc7-49ad56d0ea3e'	System	28 Aug 2020 02:06:04
User entered 'No (N)'	System	28 Aug 2020 02:06:04

FDA-CBER-2022-1614-2660253

US3542053
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 08:13:30
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-27T22:05:51', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '2debea64-f244-4391-8fc7-49ad56d0ea3e'	System	28 Aug 2020 02:06:04
User entered 'No (N)'	System	28 Aug 2020 02:06:04

FDA-CBER-2022-1614-2660254

US3542053
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 08:13:30
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 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-27T22:05:57', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '2debea64-f244-4391-8fc7-49ad56d0ea3e'	System	28 Aug 2020 02:06:04
User entered 'None (1)'	System	28 Aug 2020 02:06:04

US3542053
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 08:13:30
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-27T22:06:00', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '2debea64-f244-4391-8fc7-49ad56d0ea3e'	System	28 Aug 2020 02:06:04
User entered '27 Aug 2020 22:06'	System	28 Aug 2020 02:06:04

FDA-CBER-2022-1614-2660256

US3542053
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 08:13:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '27 Aug 2020 12:00'	System	25 Aug 2020 15:29:29

FDA-CBER-2022-1614-2660257

US3542053
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 08:13:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '28 Aug 2020 11:59'	System	25 Aug 2020 15:29:29

FDA-CBER-2022-1614-2660258

US3542053
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
Data entry locked.	System	25 Aug 2020 15:29:29
User entered 'Day 4'	System	25 Aug 2020 15:29:29

FDA-CBER-2022-1614-2660259

US3542053
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 08:13:30
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 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-28T22:32:52', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '5913603f-721e-413a-8406-262fd6cc169f'	System	29 Aug 2020 02:33:18
User entered 'None (1)'	System	29 Aug 2020 02:33:18

FDA-CBER-2022-1614-2660260

US3542053
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 08:13:30
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-28T22:32:58', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '5913603f-721e-413a-8406-262fd6cc169f'	System	29 Aug 2020 02:33:18
User entered 'No (N)'	System	29 Aug 2020 02:33:18

FDA-CBER-2022-1614-2660261

US3542053
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 08:13:30
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-28T22:33:02', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '5913603f-721e-413a-8406-262fd6cc169f'	System	29 Aug 2020 02:33:18
User entered 'No (N)'	System	29 Aug 2020 02:33:18

FDA-CBER-2022-1614-2660262

US3542053
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 08:13:30
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 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-28T22:33:12', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '5913603f-721e-413a-8406-262fd6cc169f'	System	29 Aug 2020 02:33:18
User entered 'None (1)'	System	29 Aug 2020 02:33:18

FDA-CBER-2022-1614-2660263

US3542053
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 08:13:30
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-28T22:33:15', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '5913603f-721e-413a-8406-262fd6cc169f'	System	29 Aug 2020 02:33:18
User entered '28 Aug 2020 22:33'	System	29 Aug 2020 02:33:18

US3542053
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 08:13:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '28 Aug 2020 12:00'	System	25 Aug 2020 15:29:29

FDA-CBER-2022-1614-2660265

US3542053
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 08:13:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '29 Aug 2020 11:59'	System	25 Aug 2020 15:29:29

FDA-CBER-2022-1614-2660266

US3542053
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
Data entry locked.	System	25 Aug 2020 15:29:29
User entered 'Day 5'	System	25 Aug 2020 15:29:29

FDA-CBER-2022-1614-2660267

US3542053
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 08:13:30
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 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-30T00:05:55', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '9fbb26c3-2171-4d4e-a436-d041f3a3ff7b'	System	30 Aug 2020 04:06:10
User entered 'None (1)'	System	30 Aug 2020 04:06:10

FDA-CBER-2022-1614-2660268

US3542053
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 08:13:30
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-30T00:05:59', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '9fbb26c3-2171-4d4e-a436-d041f3a3ff7b'	System	30 Aug 2020 04:06:10
User entered 'No (N)'	System	30 Aug 2020 04:06:10

US3542053
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 08:13:30
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-30T00:06:01', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '9fbb26c3-2171-4d4e-a436-d041f3a3ff7b'	System	30 Aug 2020 04:06:10
User entered 'No (N)'	System	30 Aug 2020 04:06:10

FDA-CBER-2022-1614-2660270

US3542053
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 08:13:30
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 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-30T00:06:04', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '9fbb26c3-2171-4d4e-a436-d041f3a3ff7b'	System	30 Aug 2020 04:06:10
User entered 'None (1)'	System	30 Aug 2020 04:06:10

FDA-CBER-2022-1614-2660271

US3542053
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 08:13:30
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-30T00:06:07', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '9fbb26c3-2171-4d4e-a436-d041f3a3ff7b'	System	30 Aug 2020 04:06:10
User entered '30 Aug 2020 00:06'	System	30 Aug 2020 04:06:10

FDA-CBER-2022-1614-2660272

US3542053
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 08:13:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '29 Aug 2020 12:00'	System	25 Aug 2020 15:29:29

FDA-CBER-2022-1614-2660273

US3542053
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 08:13:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '30 Aug 2020 11:59'	System	25 Aug 2020 15:29:29

FDA-CBER-2022-1614-2660274

US3542053
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
Data entry locked.	System	25 Aug 2020 15:29:29
User entered 'Day 6'	System	25 Aug 2020 15:29:29

FDA-CBER-2022-1614-2660275

US3542053
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 08:13:30
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 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-30T22:02:03', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '6baaa438-f14e-4466-91fa-418a9f58577b'	System	31 Aug 2020 02:02:20
User entered 'None (1)'	System	31 Aug 2020 02:02:20

FDA-CBER-2022-1614-2660276

US3542053
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 08:13:30
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-30T22:02:07', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '6baaa438-f14e-4466-91fa-418a9f58577b'	System	31 Aug 2020 02:02:20
User entered 'No (N)'	System	31 Aug 2020 02:02:20

US3542053
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 08:13:30
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-30T22:02:11', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '6baaa438-f14e-4466-91fa-418a9f58577b'	System	31 Aug 2020 02:02:20
User entered 'No (N)'	System	31 Aug 2020 02:02:20

FDA-CBER-2022-1614-2660278

US3542053
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 08:13:30
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 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-30T22:02:15', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '6baaa438-f14e-4466-91fa-418a9f58577b'	System	31 Aug 2020 02:02:20
User entered 'None (1)'	System	31 Aug 2020 02:02:20

FDA-CBER-2022-1614-2660279

US3542053
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 08:13:30
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-30T22:02:18', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '6baaa438-f14e-4466-91fa-418a9f58577b'	System	31 Aug 2020 02:02:20
User entered '30 Aug 2020 22:02'	System	31 Aug 2020 02:02:20

US3542053
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 08:13:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '30 Aug 2020 12:00'	System	25 Aug 2020 15:29:29

FDA-CBER-2022-1614-2660281

US3542053
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 08:13:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '31 Aug 2020 11:59'	System	25 Aug 2020 15:29:29

FDA-CBER-2022-1614-2660282

US3542053
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
Data entry locked.	System	25 Aug 2020 15:29:29
User entered 'Day 7'	System	25 Aug 2020 15:29:29

FDA-CBER-2022-1614-2660283

US3542053
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 08:13:30
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 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-31T22:56:44', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '7215febe-c87a-403e-b648-625fe5b08c49'	System	01 Sep 2020 02:57:00
User entered 'None (1)'	System	01 Sep 2020 02:57:00

US3542053
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 08:13:30
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-31T22:56:47', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '7215febe-c87a-403e-b648-625fe5b08c49'	System	01 Sep 2020 02:57:00
User entered 'No (N)'	System	01 Sep 2020 02:57:00

US3542053
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 08:13:30
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-31T22:56:50', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '7215febe-c87a-403e-b648-625fe5b08c49'	System	01 Sep 2020 02:57:00
User entered 'No (N)'	System	01 Sep 2020 02:57:00

US3542053
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 08:13:30
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 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-31T22:56:54', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '7215febe-c87a-403e-b648-625fe5b08c49'	System	01 Sep 2020 02:57:00
User entered 'None (1)'	System	01 Sep 2020 02:57:00

FDA-CBER-2022-1614-2660287

US3542053
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 08:13:30
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-31T22:56:57', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '7215febe-c87a-403e-b648-625fe5b08c49'	System	01 Sep 2020 02:57:00
User entered '31 Aug 2020 22:56'	System	01 Sep 2020 02:57:00

US3542053
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 08:13:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '31 Aug 2020 12:00'	System	25 Aug 2020 15:29:29

FDA-CBER-2022-1614-2660289

US3542053
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 08:13:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '01 Sep 2020 11:59'	System	25 Aug 2020 15:29:29

FDA-CBER-2022-1614-2660290

US3542053
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
Data entry locked.	System	25 Aug 2020 15:29:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Aug 2020 15:29:29

US3542053
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 08:13:30
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-25T11:34:54', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'a661865e-5dea-4a16-8dd2-e70b447b7d02'	System	26 Aug 2020 01:07:18
User entered 'None (0)'	System	26 Aug 2020 01:07:18

FDA-CBER-2022-1614-2660292

US3542053
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 08:13:30
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-25T11:34:58', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'a661865e-5dea-4a16-8dd2-e70b447b7d02'	System	26 Aug 2020 01:07:18
User entered 'None (0)'	System	26 Aug 2020 01:07:18

FDA-CBER-2022-1614-2660293

US3542053
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 08:13:30
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-25T11:35:02', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'a661865e-5dea-4a16-8dd2-e70b447b7d02'	System	26 Aug 2020 01:07:18
User entered 'None (0)'	System	26 Aug 2020 01:07:18

FDA-CBER-2022-1614-2660294

US3542053
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 08:13:30
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-25T11:35:06', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'a661865e-5dea-4a16-8dd2-e70b447b7d02'	System	26 Aug 2020 01:07:18
User entered 'None (0)'	System	26 Aug 2020 01:07:18

FDA-CBER-2022-1614-2660295

US3542053
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 08:13:30
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-25T11:35:09', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'a661865e-5dea-4a16-8dd2-e70b447b7d02'	System	26 Aug 2020 01:07:18
User entered 'None (0)'	System	26 Aug 2020 01:07:18

FDA-CBER-2022-1614-2660296

US3542053
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 08:13:30
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-25T11:35:12', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'a661865e-5dea-4a16-8dd2-e70b447b7d02'	System	26 Aug 2020 01:07:18
User entered 'None (0)'	System	26 Aug 2020 01:07:18

FDA-CBER-2022-1614-2660297

US3542053
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 08:13:30
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-25T11:35:20', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'a661865e-5dea-4a16-8dd2-e70b447b7d02'	System	26 Aug 2020 01:07:18
User entered 'No (N)'	System	26 Aug 2020 01:07:18

FDA-CBER-2022-1614-2660298

US3542053
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 08:13:30
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-25T11:35:25', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'a661865e-5dea-4a16-8dd2-e70b447b7d02'	System	26 Aug 2020 01:07:18
User entered '25 Aug 2020 11:35'	System	26 Aug 2020 01:07:18

FDA-CBER-2022-1614-2660299

US3542053
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 08:13:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '25 Aug 2020 11:19'	System	25 Aug 2020 15:29:29

FDA-CBER-2022-1614-2660300

US3542053
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 08:13:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '25 Aug 2020 13:49'	System	25 Aug 2020 15:29:29

FDA-CBER-2022-1614-2660301

US3542053
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
Data entry locked.	System	25 Aug 2020 15:29:29
User entered 'Day 1, after vaccination (at home)'	System	25 Aug 2020 15:29:29

US3542053
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 08:13:30
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-25T22:01:30', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'df7d128d-1a75-4552-8b34-4add04f3e670'	System	26 Aug 2020 02:02:15
User entered 'None (0)'	System	26 Aug 2020 02:02:15

FDA-CBER-2022-1614-2660303

US3542053
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 08:13:30
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-25T22:01:34', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'df7d128d-1a75-4552-8b34-4add04f3e670'	System	26 Aug 2020 02:02:15
User entered 'None (0)'	System	26 Aug 2020 02:02:15

FDA-CBER-2022-1614-2660304

US3542053
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 08:13:30
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-25T22:01:38', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'df7d128d-1a75-4552-8b34-4add04f3e670'	System	26 Aug 2020 02:02:15
User entered 'None (0)'	System	26 Aug 2020 02:02:15

FDA-CBER-2022-1614-2660305

US3542053
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 08:13:30
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-25T22:01:42', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'df7d128d-1a75-4552-8b34-4add04f3e670'	System	26 Aug 2020 02:02:15
User entered 'None (0)'	System	26 Aug 2020 02:02:15

FDA-CBER-2022-1614-2660306

US3542053
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 08:13:30
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-25T22:01:45', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'df7d128d-1a75-4552-8b34-4add04f3e670'	System	26 Aug 2020 02:02:15
User entered 'None (0)'	System	26 Aug 2020 02:02:15

FDA-CBER-2022-1614-2660307

US3542053
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 08:13:30
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-25T22:01:48', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'df7d128d-1a75-4552-8b34-4add04f3e670'	System	26 Aug 2020 02:02:15
User entered 'None (0)'	System	26 Aug 2020 02:02:15

US3542053
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 08:13:30
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-25T22:01:54', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'df7d128d-1a75-4552-8b34-4add04f3e670'	System	26 Aug 2020 02:02:15
User entered 'No (N)'	System	26 Aug 2020 02:02:15

FDA-CBER-2022-1614-2660309

US3542053
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 08:13:30
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-25T22:02:11', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'df7d128d-1a75-4552-8b34-4add04f3e670'	System	26 Aug 2020 02:02:15
User entered '25 Aug 2020 22:02'	System	26 Aug 2020 02:02:15

FDA-CBER-2022-1614-2660310

US3542053
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 08:13:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '25 Aug 2020 14:44'	System	25 Aug 2020 15:29:29

FDA-CBER-2022-1614-2660311

US3542053
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 08:13:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '26 Aug 2020 11:59'	System	25 Aug 2020 15:29:29

FDA-CBER-2022-1614-2660312

US3542053
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
Data entry locked.	System	25 Aug 2020 15:29:29
User entered 'Day 2'	System	25 Aug 2020 15:29:29

US3542053
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 08:13:30
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-26T21:58:22', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '13ad783b-3576-44b1-9f18-0692e6b91699'	System	27 Aug 2020 01:58:50
User entered 'None (0)'	System	27 Aug 2020 01:58:50

FDA-CBER-2022-1614-2660314

US3542053
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 08:13:30
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-26T21:58:25', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '13ad783b-3576-44b1-9f18-0692e6b91699'	System	27 Aug 2020 01:58:50
User entered 'None (0)'	System	27 Aug 2020 01:58:50

US3542053
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 08:13:30
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-26T21:58:27', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '13ad783b-3576-44b1-9f18-0692e6b91699'	System	27 Aug 2020 01:58:50
User entered 'None (0)'	System	27 Aug 2020 01:58:50

US3542053
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 08:13:30
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-26T21:58:31', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '13ad783b-3576-44b1-9f18-0692e6b91699'	System	27 Aug 2020 01:58:50
User entered 'None (0)'	System	27 Aug 2020 01:58:50

FDA-CBER-2022-1614-2660317

US3542053
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 08:13:30
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-26T21:58:34', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '13ad783b-3576-44b1-9f18-0692e6b91699'	System	27 Aug 2020 01:58:50
User entered 'None (0)'	System	27 Aug 2020 01:58:50

FDA-CBER-2022-1614-2660318

US3542053
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 08:13:30
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-26T21:58:36', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '13ad783b-3576-44b1-9f18-0692e6b91699'	System	27 Aug 2020 01:58:50
User entered 'None (0)'	System	27 Aug 2020 01:58:50

FDA-CBER-2022-1614-2660319

US3542053
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 08:13:30
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-26T21:58:40', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '13ad783b-3576-44b1-9f18-0692e6b91699'	System	27 Aug 2020 01:58:50
User entered 'No (N)'	System	27 Aug 2020 01:58:50

US3542053
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 08:13:30
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-26T21:58:46', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '13ad783b-3576-44b1-9f18-0692e6b91699'	System	27 Aug 2020 01:58:50
User entered '26 Aug 2020 21:58'	System	27 Aug 2020 01:58:50

FDA-CBER-2022-1614-2660321

US3542053
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 08:13:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '26 Aug 2020 12:00'	System	25 Aug 2020 15:29:29

FDA-CBER-2022-1614-2660322

US3542053
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 08:13:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '27 Aug 2020 11:59'	System	25 Aug 2020 15:29:29

FDA-CBER-2022-1614-2660323

US3542053
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
Data entry locked.	System	25 Aug 2020 15:29:29
User entered 'Day 3'	System	25 Aug 2020 15:29:29

FDA-CBER-2022-1614-2660324

US3542053
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 08:13:30
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-27T22:06:08', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'acfa6f52-e519-45e7-9623-c74edb61169e'	System	28 Aug 2020 02:06:38
User entered 'None (0)'	System	28 Aug 2020 02:06:38

FDA-CBER-2022-1614-2660325

US3542053
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 08:13:30
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-27T22:06:10', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'acfa6f52-e519-45e7-9623-c74edb61169e'	System	28 Aug 2020 02:06:38
User entered 'None (0)'	System	28 Aug 2020 02:06:38

US3542053
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 08:13:30
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-27T22:06:13', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'acfa6f52-e519-45e7-9623-c74edb61169e'	System	28 Aug 2020 02:06:38
User entered 'None (0)'	System	28 Aug 2020 02:06:38

FDA-CBER-2022-1614-2660327

US3542053
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 08:13:30
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-27T22:06:18', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'acfa6f52-e519-45e7-9623-c74edb61169e'	System	28 Aug 2020 02:06:38
User entered 'None (0)'	System	28 Aug 2020 02:06:38

FDA-CBER-2022-1614-2660328

US3542053
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 08:13:30
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-27T22:06:20', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'acfa6f52-e519-45e7-9623-c74edb61169e'	System	28 Aug 2020 02:06:38
User entered 'None (0)'	System	28 Aug 2020 02:06:38

FDA-CBER-2022-1614-2660329

US3542053
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 08:13:30
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-27T22:06:22', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'acfa6f52-e519-45e7-9623-c74edb61169e'	System	28 Aug 2020 02:06:38
User entered 'None (0)'	System	28 Aug 2020 02:06:38

FDA-CBER-2022-1614-2660330

US3542053
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 08:13:30
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-27T22:06:29', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'acfa6f52-e519-45e7-9623-c74edb61169e'	System	28 Aug 2020 02:06:38
User entered 'No (N)'	System	28 Aug 2020 02:06:38

FDA-CBER-2022-1614-2660331

US3542053
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 08:13:30
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-27T22:06:33', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'acfa6f52-e519-45e7-9623-c74edb61169e'	System	28 Aug 2020 02:06:38
User entered '27 Aug 2020 22:06'	System	28 Aug 2020 02:06:38

US3542053
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 08:13:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '27 Aug 2020 12:00'	System	25 Aug 2020 15:29:29

FDA-CBER-2022-1614-2660333

US3542053
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 08:13:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '28 Aug 2020 11:59'	System	25 Aug 2020 15:29:29

FDA-CBER-2022-1614-2660334

US3542053
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
Data entry locked.	System	25 Aug 2020 15:29:29
User entered 'Day 4'	System	25 Aug 2020 15:29:29

US3542053
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 08:13:30
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49

FDA-CBER-2022-1614-2660336

US3542053
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 08:13:30
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49

FDA-CBER-2022-1614-2660337

US3542053
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 08:13:30
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49

FDA-CBER-2022-1614-2660338

US3542053
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 08:13:30
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49

FDA-CBER-2022-1614-2660339

US3542053
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 08:13:30
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49

FDA-CBER-2022-1614-2660340

US3542053
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 08:13:30
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49

FDA-CBER-2022-1614-2660341

US3542053
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 08:13:30
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49

FDA-CBER-2022-1614-2660342

US3542053
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 08:13:30
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49

FDA-CBER-2022-1614-2660343

US3542053
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 08:13:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '28 Aug 2020 12:00'	System	25 Aug 2020 15:29:29

FDA-CBER-2022-1614-2660344

US3542053
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 08:13:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '29 Aug 2020 11:59'	System	25 Aug 2020 15:29:29

FDA-CBER-2022-1614-2660345

US3542053
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
Data entry locked.	System	25 Aug 2020 15:29:29
User entered 'Day 5'	System	25 Aug 2020 15:29:29

FDA-CBER-2022-1614-2660346

US3542053
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 08:13:30
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-30T00:06:14', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'b83a2a0a-621e-4279-97b4-592d17a72b70'	System	30 Aug 2020 04:06:34
User entered 'None (0)'	System	30 Aug 2020 04:06:34

FDA-CBER-2022-1614-2660347

US3542053
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 08:13:30
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-30T00:06:16', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'b83a2a0a-621e-4279-97b4-592d17a72b70'	System	30 Aug 2020 04:06:34
User entered 'None (0)'	System	30 Aug 2020 04:06:34

FDA-CBER-2022-1614-2660348

US3542053
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 08:13:30
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-30T00:06:18', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'b83a2a0a-621e-4279-97b4-592d17a72b70'	System	30 Aug 2020 04:06:34
User entered 'None (0)'	System	30 Aug 2020 04:06:34

FDA-CBER-2022-1614-2660349

US3542053
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 08:13:30
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-30T00:06:20', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'b83a2a0a-621e-4279-97b4-592d17a72b70'	System	30 Aug 2020 04:06:34
User entered 'None (0)'	System	30 Aug 2020 04:06:34

FDA-CBER-2022-1614-2660350

US3542053
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 08:13:30
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-30T00:06:21', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'b83a2a0a-621e-4279-97b4-592d17a72b70'	System	30 Aug 2020 04:06:34
User entered 'None (0)'	System	30 Aug 2020 04:06:34

FDA-CBER-2022-1614-2660351

US3542053
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 08:13:30
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-30T00:06:23', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'b83a2a0a-621e-4279-97b4-592d17a72b70'	System	30 Aug 2020 04:06:34
User entered 'None (0)'	System	30 Aug 2020 04:06:34

FDA-CBER-2022-1614-2660352

US3542053
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 08:13:30
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-30T00:06:28', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'b83a2a0a-621e-4279-97b4-592d17a72b70'	System	30 Aug 2020 04:06:34
User entered 'No (N)'	System	30 Aug 2020 04:06:34

FDA-CBER-2022-1614-2660353

US3542053
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 08:13:30
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-30T00:06:32', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'b83a2a0a-621e-4279-97b4-592d17a72b70'	System	30 Aug 2020 04:06:34
User entered '30 Aug 2020 00:06'	System	30 Aug 2020 04:06:34

US3542053
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 08:13:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '29 Aug 2020 12:00'	System	25 Aug 2020 15:29:29

FDA-CBER-2022-1614-2660355

US3542053
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 08:13:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '30 Aug 2020 11:59'	System	25 Aug 2020 15:29:29

FDA-CBER-2022-1614-2660356

US3542053
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
Data entry locked.	System	25 Aug 2020 15:29:29
User entered 'Day 6'	System	25 Aug 2020 15:29:29

FDA-CBER-2022-1614-2660357

US3542053
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 08:13:30
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-30T22:02:23', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'a331550e-4733-48fa-915e-96644b3c9805'	System	31 Aug 2020 02:02:52
User entered 'None (0)'	System	31 Aug 2020 02:02:52

FDA-CBER-2022-1614-2660358

US3542053
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 08:13:30
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-30T22:02:27', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'a331550e-4733-48fa-915e-96644b3c9805'	System	31 Aug 2020 02:02:52
User entered 'None (0)'	System	31 Aug 2020 02:02:52

FDA-CBER-2022-1614-2660359

US3542053
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 08:13:30
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-30T22:02:31', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'a331550e-4733-48fa-915e-96644b3c9805'	System	31 Aug 2020 02:02:52
User entered 'None (0)'	System	31 Aug 2020 02:02:52

FDA-CBER-2022-1614-2660360

US3542053
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 08:13:30
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-30T22:02:35', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'a331550e-4733-48fa-915e-96644b3c9805'	System	31 Aug 2020 02:02:52
User entered 'None (0)'	System	31 Aug 2020 02:02:52

FDA-CBER-2022-1614-2660361

US3542053
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 08:13:30
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-30T22:02:38', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'a331550e-4733-48fa-915e-96644b3c9805'	System	31 Aug 2020 02:02:52
User entered 'None (0)'	System	31 Aug 2020 02:02:52

FDA-CBER-2022-1614-2660362

US3542053
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 08:13:30
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-30T22:02:40', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'a331550e-4733-48fa-915e-96644b3c9805'	System	31 Aug 2020 02:02:52
User entered 'None (0)'	System	31 Aug 2020 02:02:52

FDA-CBER-2022-1614-2660363

US3542053
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 08:13:30
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-30T22:02:46', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'a331550e-4733-48fa-915e-96644b3c9805'	System	31 Aug 2020 02:02:52
User entered 'No (N)'	System	31 Aug 2020 02:02:52

FDA-CBER-2022-1614-2660364

US3542053
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 08:13:30
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-30T22:02:49', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'a331550e-4733-48fa-915e-96644b3c9805'	System	31 Aug 2020 02:02:52
User entered '30 Aug 2020 22:02'	System	31 Aug 2020 02:02:52

FDA-CBER-2022-1614-2660365

US3542053
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 08:13:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '30 Aug 2020 12:00'	System	25 Aug 2020 15:29:29

FDA-CBER-2022-1614-2660366

US3542053
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 08:13:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '31 Aug 2020 11:59'	System	25 Aug 2020 15:29:29

FDA-CBER-2022-1614-2660367

US3542053
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
Data entry locked.	System	25 Aug 2020 15:29:29
User entered 'Day 7'	System	25 Aug 2020 15:29:29

FDA-CBER-2022-1614-2660368

US3542053
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 08:13:30
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-31T22:57:03', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'ab0dfae9-69f3-4ced-93a6-827898abc541'	System	01 Sep 2020 02:57:28
User entered 'None (0)'	System	01 Sep 2020 02:57:28

US3542053
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 08:13:30
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-31T22:57:06', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'ab0dfae9-69f3-4ced-93a6-827898abc541'	System	01 Sep 2020 02:57:28
User entered 'None (0)'	System	01 Sep 2020 02:57:28

FDA-CBER-2022-1614-2660370

US3542053
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 08:13:30
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-31T22:57:11', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'ab0dfae9-69f3-4ced-93a6-827898abc541'	System	01 Sep 2020 02:57:28
User entered 'None (0)'	System	01 Sep 2020 02:57:28

FDA-CBER-2022-1614-2660371

US3542053
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 08:13:30
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-31T22:57:14', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'ab0dfae9-69f3-4ced-93a6-827898abc541'	System	01 Sep 2020 02:57:28
User entered 'None (0)'	System	01 Sep 2020 02:57:28

FDA-CBER-2022-1614-2660372

US3542053
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 08:13:30
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-31T22:57:16', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'ab0dfae9-69f3-4ced-93a6-827898abc541'	System	01 Sep 2020 02:57:28
User entered 'None (0)'	System	01 Sep 2020 02:57:28

FDA-CBER-2022-1614-2660373

US3542053
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 08:13:30
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-31T22:57:19', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'ab0dfae9-69f3-4ced-93a6-827898abc541'	System	01 Sep 2020 02:57:28
User entered 'None (0)'	System	01 Sep 2020 02:57:28

FDA-CBER-2022-1614-2660374

US3542053
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 08:13:30
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-31T22:57:23', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'ab0dfae9-69f3-4ced-93a6-827898abc541'	System	01 Sep 2020 02:57:28
User entered 'No (N)'	System	01 Sep 2020 02:57:28

FDA-CBER-2022-1614-2660375

US3542053
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 08:13:30
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-08-31T22:57:26', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'ab0dfae9-69f3-4ced-93a6-827898abc541'	System	01 Sep 2020 02:57:28
User entered '31 Aug 2020 22:57'	System	01 Sep 2020 02:57:28

US3542053
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 08:13:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '31 Aug 2020 12:00'	System	25 Aug 2020 15:29:29

FDA-CBER-2022-1614-2660377

US3542053
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 08:13:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '01 Sep 2020 11:59'	System	25 Aug 2020 15:29:29

FDA-CBER-2022-1614-2660378

US3542053
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 10 Jun 2021 08:13:30
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 15:30:59
User entered 'Yes (Y)'	Taylor Ladson (b) (4) (b) (4)	03 Sep 2020 15:50:25

US3542053
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 10 Jun 2021 08:13:30
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 15:30:59
User entered '2 Sep 2020'	Taylor Ladson (b) (4) (b) (4)	03 Sep 2020 15:50:25

US3542053
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 10 Jun 2021 08:13:30
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4)	05 Sep 2020 15:30:59
User entered 'Contact Made (CONTACT MADE)'	Taylor Ladson (b) (4) (b) (4)	03 Sep 2020 15:50:25

FDA-CBER-2022-1614-2660381

US3542053
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 10 Jun 2021 08:13:30
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 15:30:59
User entered empty.	Taylor Ladson (b) (4) (b) (4)	03 Sep 2020 15:50:25

US3542053
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 10 Jun 2021 08:13:30
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 15:30:59
User entered 'Yes (Y)'	Taylor Ladson (b) (4) (b) (4)	03 Sep 2020 15:51:24

FDA-CBER-2022-1614-2660383

US3542053
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 10 Jun 2021 08:13:30
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User entered '1'	System	03 Sep 2020 15:51:24

FDA-CBER-2022-1614-2660384

US3542053
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 10 Jun 2021 08:13:30
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	14 Sep 2020 04:51:57
User entered 'Yes (Y)'	Taylor Ladson (b) (4) (b) (4)	10 Sep 2020 16:27:35

FDA-CBER-2022-1614-2660385

US3542053
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 10 Jun 2021 08:13:30
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	14 Sep 2020 04:51:57
User entered '9 Sep 2020'	Taylor Ladson (b) (4) (b) (4)	10 Sep 2020 16:27:35

US3542053
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 10 Jun 2021 08:13:30
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	14 Sep 2020 04:51:57
User entered 'Contact Made (CONTACT MADE)'	Taylor Ladson (b) (4) (b) (4)	10 Sep 2020 16:27:35

US3542053
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 10 Jun 2021 08:13:30
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	14 Sep 2020 04:51:57
User entered empty.	Taylor Ladson (b) (4) (b) (4)	10 Sep 2020 16:27:35

US3542053
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 10 Jun 2021 08:13:30
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	14 Sep 2020 04:51:57
User entered 'Yes (Y)'	Taylor Ladson (b) (4) (b) (4)	10 Sep 2020 16:27:41

FDA-CBER-2022-1614-2660389

US3542053
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 10 Jun 2021 08:13:30
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User entered '1'	System	10 Sep 2020 16:27:41

FDA-CBER-2022-1614-2660390

US3542053
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 10 Jun 2021 08:13:30
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	23 Sep 2020 15:17:42
User entered 'Yes (Y)'	Taylor Ladson (b) (4) (b) (4)	17 Sep 2020 15:09:47

US3542053
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 10 Jun 2021 08:13:30
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	23 Sep 2020 15:17:42
User entered '16 Sep 2020'	Taylor Ladson (b) (4) (b) (4)	17 Sep 2020 15:09:47

US3542053
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 10 Jun 2021 08:13:30
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	23 Sep 2020 15:17:42
User entered 'Contact Made (CONTACT MADE)'	Taylor Ladson (b) (4) (b) (4)	17 Sep 2020 15:09:47

US3542053
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 10 Jun 2021 08:13:30
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	23 Sep 2020 15:17:42
User entered empty.	Taylor Ladson (b) (4) (b) (4)	17 Sep 2020 15:09:47

US3542053
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 10 Jun 2021 08:13:30
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	23 Sep 2020 15:17:42
User entered 'Yes (Y)'	Taylor Ladson (b) (4) (b) (4)	17 Sep 2020 15:09:53

US3542053
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 10 Jun 2021 08:13:30
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User entered '1'	System	17 Sep 2020 15:09:53

FDA-CBER-2022-1614-2660396

US3542053
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 10 Jun 2021 08:13:30
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:17:42
User entered 'Yes (Y)'	Madhu Balachandran (b) (4)	22 Sep 2020 18:31:40

FDA-CBER-2022-1614-2660397

US3542053
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 10 Jun 2021 08:13:30
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	23 Sep 2020 15:17:42
User entered '21 Sep 2020'	Madhu Balachandran (b) (4)	22 Sep 2020 18:31:40

FDA-CBER-2022-1614-2660398

US3542053
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 10 Jun 2021 08:13:30
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	23 Sep 2020 15:17:42
User entered 'Clinic (Clinic)'	Madhu Balachandran (b) (4)	22 Sep 2020 18:31:40

US3542053
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 10 Jun 2021 08:13:30
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User entered 'VISIT2'	System	22 Sep 2020 18:31:40

FDA-CBER-2022-1614-2660400

US3542053
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 08:13:30
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User accepted default value 'Pre-Dose (PREDOSE)'	Madhu Balachandran (b) (4)	22 Sep 2020 18:33:05

FDA-CBER-2022-1614-2660401

US3542053
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 08:13:30
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Oct 2020 15:28:20
User entered 'Yes (Y)'	Madhu Balachandran (b) (4)	22 Sep 2020 18:33:05

FDA-CBER-2022-1614-2660402

US3542053
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 08:13:30
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Oct 2020 15:28:20
User entered '21 Sep 2020'	Madhu Balachandran (b) (4)	22 Sep 2020 18:33:05

FDA-CBER-2022-1614-2660403

US3542053
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 08:13:30
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:28:20
User entered '09:03'	Madhu Balachandran (b) (4)	22 Sep 2020 18:33:05

US3542053
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 08:13:30
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User entered '21 Sep 2020 09:03'	System	22 Sep 2020 18:33:05

FDA-CBER-2022-1614-2660405

US3542053
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 08:13:30
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:28:20
User entered '98.1' F	Madhu Balachandran (b) (4)	22 Sep 2020 18:33:05

US3542053
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 08:13:30
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:28:20
User entered 'Oral (Oral)'	Madhu Balachandran (b) (4)	22 Sep 2020 18:33:05

FDA-CBER-2022-1614-2660407

US3542053
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 08:13:30
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:28:20
User entered empty.	(b) (4) Madhu Balachandran (b) (4)	22 Sep 2020 18:33:05

FDA-CBER-2022-1614-2660408

US3542053
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 08:13:30
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:28:20
User entered '68'	Madhu Balachandran (b) (4)	22 Sep 2020 18:33:05

US3542053
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 08:13:30
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User entered 'bpm'	System	22 Sep 2020 18:33:05

FDA-CBER-2022-1614-2660410

US3542053
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 08:13:30
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Oct 2020 15:28:20
User entered '16'	Madhu Balachandran (b) (4)	22 Sep 2020 18:33:05

US3542053
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 08:13:30
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User entered 'breaths/min'	System	22 Sep 2020 18:33:05

FDA-CBER-2022-1614-2660412

US3542053
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 08:13:30
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:28:20
User entered '122'	Madhu Balachandran (b) (4)	22 Sep 2020 18:33:05

US3542053
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 08:13:30
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User entered 'mmHg'	System	22 Sep 2020 18:33:05

FDA-CBER-2022-1614-2660414

US3542053
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 08:13:30
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	05 Oct 2020 06:37:43
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:28:20
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	(b) (4) Hannah Yellin (b) (4) (b) (4)	01 Oct 2020 18:48:08
User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	22 Sep 2020 18:33:05
User entered '53'	Madhu Balachandran (b) (4)	22 Sep 2020 18:33:05

US3542053
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 08:13:30
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User entered 'mmHg'	System	22 Sep 2020 18:33:05

FDA-CBER-2022-1614-2660416

US3542053
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 08:13:30
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User accepted default value 'Post-Dose (POSTDOSE)'	Madhu Balachandran (b) (4)	22 Sep 2020 18:33:05

FDA-CBER-2022-1614-2660417

US3542053
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 08:13:30
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Oct 2020 15:28:20
User entered 'Yes (Y)'	Madhu Balachandran (b) (4)	22 Sep 2020 18:33:05

FDA-CBER-2022-1614-2660418

US3542053
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 08:13:30
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Oct 2020 15:28:20
User entered '21 Sep 2020'	Madhu Balachandran (b) (4)	22 Sep 2020 18:33:05

FDA-CBER-2022-1614-2660419

US3542053
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 08:13:30
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:28:20
User entered '10:35'	Madhu Balachandran (b) (4)	22 Sep 2020 18:33:05

FDA-CBER-2022-1614-2660420

US3542053
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 08:13:30
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User entered '21 Sep 2020 10:35'	System	22 Sep 2020 18:33:05

FDA-CBER-2022-1614-2660421

US3542053
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 08:13:30
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Oct 2020 15:28:20
User entered '98.1' F	Madhu Balachandran (b) (4)	22 Sep 2020 18:33:05

US3542053
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 08:13:30
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:28:20
User entered 'Oral (Oral)'	Madhu Balachandran (b) (4)	22 Sep 2020 18:33:05

US3542053
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 08:13:30
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:28:20
User entered empty.	(b) (4) Madhu Balachandran (b) (4)	22 Sep 2020 18:33:05

FDA-CBER-2022-1614-2660424

US3542053
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 08:13:30
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:28:20
User entered '63'	Madhu Balachandran (b) (4)	22 Sep 2020 18:33:05

US3542053
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 08:13:30
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User entered 'bpm'	System	22 Sep 2020 18:33:05

FDA-CBER-2022-1614-2660426

US3542053
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 08:13:30
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:28:20
User entered '16'	Madhu Balachandran (b) (4)	22 Sep 2020 18:33:05

US3542053
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 08:13:30
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User entered 'breaths/min'	System	22 Sep 2020 18:33:05

FDA-CBER-2022-1614-2660428

US3542053
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 08:13:30
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:28:20
User entered '123'	Madhu Balachandran (b) (4)	22 Sep 2020 18:33:05

FDA-CBER-2022-1614-2660429

US3542053
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 08:13:30
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User entered 'mmHg'	System	22 Sep 2020 18:33:05

FDA-CBER-2022-1614-2660430

US3542053
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 08:13:30
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	05 Oct 2020 06:38:04
User signature succeeded.	David Diemert (b) (4)	03 Oct 2020 15:28:20
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	(b) (4) Hannah Yellin (b) (4) (b) (4)	01 Oct 2020 18:48:16
User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	22 Sep 2020 18:33:05
User entered '57'	Madhu Balachandran (b) (4)	22 Sep 2020 18:33:05

FDA-CBER-2022-1614-2660431

US3542053
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 08:13:30
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User entered 'mmHg'	System	22 Sep 2020 18:33:05

FDA-CBER-2022-1614-2660432

US3542053
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Generated On: 10 Jun 2021 08:13:30
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	23 Sep 2020 15:17:42
User entered 'Yes (Y)'	Madhu Balachandran (b) (4)	22 Sep 2020 18:41:12

US3542053
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Generated On: 10 Jun 2021 08:13:30
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:17:42
User entered '21 Sep 2020'	Madhu Balachandran (b) (4)	22 Sep 2020 18:41:12

FDA-CBER-2022-1614-2660434

US3542053
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 08:13:30
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	23 Sep 2020 15:17:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 14:15:56

US3542053
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 08:13:30
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	23 Sep 2020 15:17:42
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 14:15:56

FDA-CBER-2022-1614-2660436

US3542053
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 08:13:30
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	23 Sep 2020 15:17:42
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 14:15:56

US3542053
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 08:13:30
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User entered 'MRNA-1273 OR PLACEBO'	System	21 Sep 2020 14:15:56

US3542053
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 08:13:30
What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	23 Sep 2020 15:17:42
User entered '21 Sep 2020'	(b) (4), (b) (6)	21 Sep 2020 14:15:56

FDA-CBER-2022-1614-2660439

US3542053
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 08:13:30
What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	23 Sep 2020 15:17:42
User entered '10:04'	(b) (4), (b) (6)	21 Sep 2020 14:15:56

FDA-CBER-2022-1614-2660440

US3542053
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 08:13:30
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User entered '21 Sep 2020 10:04'	System	21 Sep 2020 14:15:56

US3542053
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 08:13:30
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	23 Sep 2020 15:17:42
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	21 Sep 2020 14:15:56

FDA-CBER-2022-1614-2660442

US3542053
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 08:13:30
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User entered 'ONCE'	System	21 Sep 2020 14:15:56

FDA-CBER-2022-1614-2660443

US3542053
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 08:13:30
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User entered 'INTRAMUSCULAR'	System	21 Sep 2020 14:15:56

US3542053
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 08:13:30
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:17:42
User entered 'Yes (Y)'	Madhu Balachandran (b) (4)	22 Sep 2020 18:41:59

FDA-CBER-2022-1614-2660445

US3542053
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 08:13:30
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	23 Sep 2020 15:17:42
User entered '21 Sep 2020'	Madhu Balachandran (b) (4)	22 Sep 2020 18:41:59

FDA-CBER-2022-1614-2660446

US3542053
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 08:13:30
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:17:42
User entered '09:28'	Madhu Balachandran (b) (4)	22 Sep 2020 18:41:59

FDA-CBER-2022-1614-2660447

US3542053
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 08:13:30
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User entered '21 Sep 2020 09:28'	System	22 Sep 2020 18:41:59

US3542053
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab
Generated On: 10 Jun 2021 08:13:30
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:17:42
User entered '21 Sep 2020'	Madhu Balachandran (b) (4)	22 Sep 2020 18:43:16

FDA-CBER-2022-1614-2660449

US3542053
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 08:13:30
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Madhu Balachandran (b) (4)	22 Sep 2020 18:43:16

US3542053
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 08:13:30
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:17:42
User entered 'Yes (Y)'	(b) (4) Madhu Balachandran (b) (4)	22 Sep 2020 18:43:16

US3542053
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 08:13:30
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Nov 2020 04:10:23
Signature has been broken.	Erika Faust (b) (4) (b) (4)	13 Nov 2020 21:42:01
User entered '09:38' reason for change: Data Entry Error	Erika Faust (b) (4) (b) (4)	13 Nov 2020 21:42:01
User signature succeeded.	David Diemert (b) (4) (b) (4)	23 Sep 2020 15:17:42
User entered '09:28'	Madhu Balachandran (b) (4)	22 Sep 2020 18:43:16

US3542053
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 08:13:30
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User entered '21 Sep 2020 09:38'	System	13 Nov 2020 21:42:01
User entered '21 Sep 2020 09:28'	System	22 Sep 2020 18:43:16

US3542053
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 08:13:30
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Madhu Balachandran (b) (4)	22 Sep 2020 18:43:16

FDA-CBER-2022-1614-2660454

US3542053
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 08:13:30
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	23 Sep 2020 15:17:42
User entered 'No (N)'	Madhu Balachandran (b) (4)	22 Sep 2020 18:43:16

US3542053
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 08:13:30
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:17:42
User entered empty.	Madhu Balachandran (b) (4)	22 Sep 2020 18:43:16

US3542053
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 08:13:30
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User entered empty.	System	22 Sep 2020 18:43:16

FDA-CBER-2022-1614-2660457

US3542053
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 10 Jun 2021 08:13:30
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:17:42
User entered 'Yes (Y)'	Madhu Balachandran (b) (4)	22 Sep 2020 18:43:19

US3542053
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 10 Jun 2021 08:13:30
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User entered '1'	System	22 Sep 2020 18:43:19

FDA-CBER-2022-1614-2660459

US3542053
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
Data entry locked.	System	21 Sep 2020 14:15:56
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 14:15:56

FDA-CBER-2022-1614-2660460

US3542053
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 08:13:30
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-21T10:39:24', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '774e98fb-2ded-48b6-a7a2-113947e238cb'	System	21 Sep 2020 14:39:42
User entered 'Yes (Y)'	System	21 Sep 2020 14:39:42

FDA-CBER-2022-1614-2660461

US3542053
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 08:13:30
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-21T10:39:31', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '774e98fb-2ded-48b6-a7a2-113947e238cb'	System	21 Sep 2020 14:39:42
User entered '98.1'	System	21 Sep 2020 14:39:42

FDA-CBER-2022-1614-2660462

US3542053
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 08:13:30
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-21T10:39:34', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '774e98fb-2ded-48b6-a7a2-113947e238cb'	System	21 Sep 2020 14:39:42
User entered 'No (N)'	System	21 Sep 2020 14:39:42

US3542053
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 08:13:30
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-21T10:39:39', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '774e98fb-2ded-48b6-a7a2-113947e238cb'	System	21 Sep 2020 14:39:42
User entered '21 Sep 2020 10:39'	System	21 Sep 2020 14:39:42

US3542053
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 08:13:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '21 Sep 2020 10:24'	System	21 Sep 2020 14:15:56

FDA-CBER-2022-1614-2660465

US3542053
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 08:13:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '21 Sep 2020 12:54'	System	21 Sep 2020 14:15:56

FDA-CBER-2022-1614-2660466

US3542053
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
Data entry locked.	System	21 Sep 2020 14:15:56
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 14:15:56

US3542053
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 08:13:30
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-21T21:32:26', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'a6ca4c11-2155-431c-a93c-29bdc7d279b2'	System	22 Sep 2020 01:32:48
User entered 'Yes (Y)'	System	22 Sep 2020 01:32:48

FDA-CBER-2022-1614-2660468

US3542053
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 08:13:30
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-21T21:32:33', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'a6ca4c11-2155-431c-a93c-29bdc7d279b2'	System	22 Sep 2020 01:32:48
User entered '97.1'	System	22 Sep 2020 01:32:48

FDA-CBER-2022-1614-2660469

US3542053
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 08:13:30
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-21T21:32:37', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'a6ca4c11-2155-431c-a93c-29bdc7d279b2'	System	22 Sep 2020 01:32:48
User entered 'No (N)'	System	22 Sep 2020 01:32:48

FDA-CBER-2022-1614-2660470

US3542053
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 08:13:30
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-21T21:32:46', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'a6ca4c11-2155-431c-a93c-29bdc7d279b2'	System	22 Sep 2020 01:32:48
User entered '21 Sep 2020 21:32'	System	22 Sep 2020 01:32:48

US3542053
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 08:13:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '21 Sep 2020 13:49'	System	21 Sep 2020 14:15:56

FDA-CBER-2022-1614-2660472

US3542053
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 08:13:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 14:15:56

FDA-CBER-2022-1614-2660473

US3542053
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
Data entry locked.	System	21 Sep 2020 14:15:56
User entered 'Day 2'	System	21 Sep 2020 14:15:56

FDA-CBER-2022-1614-2660474

US3542053
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 08:13:30
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-22T21:53:28', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '0bed0736-a43f-4397-810b-6a89e51fd26f'	System	23 Sep 2020 01:53:48
User entered 'Yes (Y)'	System	23 Sep 2020 01:53:48

FDA-CBER-2022-1614-2660475

US3542053
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 08:13:30
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-22T21:53:33', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '0bed0736-a43f-4397-810b-6a89e51fd26f'	System	23 Sep 2020 01:53:48
User entered '97.5'	System	23 Sep 2020 01:53:48

FDA-CBER-2022-1614-2660476

US3542053
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 08:13:30
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-22T21:53:37', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '0bed0736-a43f-4397-810b-6a89e51fd26f'	System	23 Sep 2020 01:53:48
User entered 'No (N)'	System	23 Sep 2020 01:53:48

FDA-CBER-2022-1614-2660477

US3542053
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 08:13:30
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-22T21:53:45', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '0bed0736-a43f-4397-810b-6a89e51fd26f'	System	23 Sep 2020 01:53:48
User entered '22 Sep 2020 21:53'	System	23 Sep 2020 01:53:48

FDA-CBER-2022-1614-2660478

US3542053
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 08:13:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 14:15:56

FDA-CBER-2022-1614-2660479

US3542053
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 08:13:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 14:15:56

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US3542053
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
Data entry locked.	System	21 Sep 2020 14:15:56
User entered 'Day 3'	System	21 Sep 2020 14:15:56

FDA-CBER-2022-1614-2660481

US3542053
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 08:13:30
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-23T21:37:20', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '43982014-0aee-484f-b794-b89fc762873a'	System	24 Sep 2020 01:38:27
User entered 'Yes (Y)'	System	24 Sep 2020 01:38:27

FDA-CBER-2022-1614-2660482

US3542053
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 08:13:30
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-23T21:38:15', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '43982014-0aee-484f-b794-b89fc762873a'	System	24 Sep 2020 01:38:27
User entered '96.8'	System	24 Sep 2020 01:38:27

FDA-CBER-2022-1614-2660483

US3542053
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 08:13:30
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-23T21:38:19', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '43982014-0aee-484f-b794-b89fc762873a'	System	24 Sep 2020 01:38:27
User entered 'No (N)'	System	24 Sep 2020 01:38:27

FDA-CBER-2022-1614-2660484

US3542053
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 08:13:30
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-23T21:38:25', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '43982014-0aee-484f-b794-b89fc762873a'	System	24 Sep 2020 01:38:27
User entered '23 Sep 2020 21:38'	System	24 Sep 2020 01:38:27

FDA-CBER-2022-1614-2660485

US3542053
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 08:13:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 14:15:56

FDA-CBER-2022-1614-2660486

US3542053
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 08:13:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 14:15:56

FDA-CBER-2022-1614-2660487

US3542053
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
Data entry locked.	System	21 Sep 2020 14:15:56
User entered 'Day 4'	System	21 Sep 2020 14:15:56

FDA-CBER-2022-1614-2660488

US3542053
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 08:13:30
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-24T21:59:48', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '4e2f238d-0434-4dc1-9333-cffd08cae76b'	System	25 Sep 2020 02:00:22
User entered 'Yes (Y)'	System	25 Sep 2020 02:00:22

FDA-CBER-2022-1614-2660489

US3542053
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 08:13:30
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-24T21:59:53', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '4e2f238d-0434-4dc1-9333-cffd08cae76b'	System	25 Sep 2020 02:00:22
User entered '97.7'	System	25 Sep 2020 02:00:22

FDA-CBER-2022-1614-2660490

US3542053
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 08:13:30
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-24T21:59:58', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '4e2f238d-0434-4dc1-9333-cffd08cae76b'	System	25 Sep 2020 02:00:22
User entered 'No (N)'	System	25 Sep 2020 02:00:22

US3542053
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 08:13:30
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-24T22:00:02', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '4e2f238d-0434-4dc1-9333-cffd08cae76b'	System	25 Sep 2020 02:00:22
User entered '24 Sep 2020 22:00'	System	25 Sep 2020 02:00:22

FDA-CBER-2022-1614-2660492

US3542053
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 08:13:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 14:15:56

FDA-CBER-2022-1614-2660493

US3542053
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 08:13:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 14:15:56

FDA-CBER-2022-1614-2660494

US3542053
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
Data entry locked.	System	21 Sep 2020 14:15:56
User entered 'Day 5'	System	21 Sep 2020 14:15:56

FDA-CBER-2022-1614-2660495

US3542053
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 08:13:30
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-25T20:58:35', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'ba830eef-15b6-4cd1-b7c4-75b2222b5e9d'	System	26 Sep 2020 00:59:09
User entered 'Yes (Y)'	System	26 Sep 2020 00:59:09

FDA-CBER-2022-1614-2660496

US3542053
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 08:13:30
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-25T20:58:46', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'ba830eef-15b6-4cd1-b7c4-75b2222b5e9d'	System	26 Sep 2020 00:59:09
User entered '99.4'	System	26 Sep 2020 00:59:09

FDA-CBER-2022-1614-2660497

US3542053
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 08:13:30
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-25T20:58:58', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'ba830eef-15b6-4cd1-b7c4-75b2222b5e9d'	System	26 Sep 2020 00:59:09
User entered 'No (N)'	System	26 Sep 2020 00:59:09

FDA-CBER-2022-1614-2660498

US3542053
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 08:13:30
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-25T20:59:04', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'ba830eef-15b6-4cd1-b7c4-75b2222b5e9d'	System	26 Sep 2020 00:59:09
User entered '25 Sep 2020 20:59'	System	26 Sep 2020 00:59:09

FDA-CBER-2022-1614-2660499

US3542053
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 08:13:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 14:15:56

FDA-CBER-2022-1614-2660500

US3542053
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 08:13:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 14:15:56

FDA-CBER-2022-1614-2660501

US3542053
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
Data entry locked.	System	21 Sep 2020 14:15:56
User entered 'Day 6'	System	21 Sep 2020 14:15:56

FDA-CBER-2022-1614-2660502

US3542053
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 08:13:30
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-26T22:04:41', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '01a80ea0-95b9-4090-ac8a-076c45f4f47e'	System	27 Sep 2020 02:05:29
User entered 'Yes (Y)'	System	27 Sep 2020 02:05:29

FDA-CBER-2022-1614-2660503

US3542053
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 08:13:30
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-26T22:04:45', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '01a80ea0-95b9-4090-ac8a-076c45f4f47e'	System	27 Sep 2020 02:05:29
User entered '97.8'	System	27 Sep 2020 02:05:29

FDA-CBER-2022-1614-2660504

US3542053
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 08:13:30
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-26T22:04:55', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '01a80ea0-95b9-4090-ac8a-076c45f4f47e'	System	27 Sep 2020 02:05:29
User entered 'Yes (Y)'	System	27 Sep 2020 02:05:29

FDA-CBER-2022-1614-2660505

US3542053
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 08:13:30
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-26T22:05:21', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '01a80ea0-95b9-4090-ac8a-076c45f4f47e'	System	27 Sep 2020 02:05:29
User entered '0'	System	27 Sep 2020 02:05:29

FDA-CBER-2022-1614-2660506

US3542053
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 08:13:30
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	05 Oct 2020 06:47:36
Query 'Per the participant response, medication was taken to prevent 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 'patient contacted' (Site from System).	DeEnna Wedding (b) (4) (b) (4)	30 Sep 2020 18:35:28
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	27 Sep 2020 02:05:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-26T22:05:21', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '01a80ea0-95b9-4090-ac8a-076c45f4f47e'	System	27 Sep 2020 02:05:29
User entered '1'	System	27 Sep 2020 02:05:29

US3542053
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 08:13:30
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-26T22:05:26', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '01a80ea0-95b9-4090-ac8a-076c45f4f47e'	System	27 Sep 2020 02:05:29
User entered '26 Sep 2020 22:05'	System	27 Sep 2020 02:05:29

FDA-CBER-2022-1614-2660508

US3542053
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 08:13:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 14:15:56

FDA-CBER-2022-1614-2660509

US3542053
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 08:13:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 14:15:56

FDA-CBER-2022-1614-2660510

US3542053
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
Data entry locked.	System	21 Sep 2020 14:15:56
User entered 'Day 7'	System	21 Sep 2020 14:15:56

FDA-CBER-2022-1614-2660511

US3542053
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 08:13:30
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-28T00:02:01', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '042780a7-a112-4344-9529-d1ee57f13571'	System	28 Sep 2020 04:02:20
User entered 'Yes (Y)'	System	28 Sep 2020 04:02:20

FDA-CBER-2022-1614-2660512

US3542053
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 08:13:30
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-28T00:02:08', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '042780a7-a112-4344-9529-d1ee57f13571'	System	28 Sep 2020 04:02:20
User entered '96.7'	System	28 Sep 2020 04:02:20

FDA-CBER-2022-1614-2660513

US3542053
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 08:13:30
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-28T00:02:12', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '042780a7-a112-4344-9529-d1ee57f13571'	System	28 Sep 2020 04:02:20
User entered 'No (N)'	System	28 Sep 2020 04:02:20

FDA-CBER-2022-1614-2660514

US3542053
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 08:13:30
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-28T00:02:17', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '042780a7-a112-4344-9529-d1ee57f13571'	System	28 Sep 2020 04:02:20
User entered '28 Sep 2020 00:02'	System	28 Sep 2020 04:02:20

US3542053
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 08:13:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 14:15:56

FDA-CBER-2022-1614-2660516

US3542053
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 08:13:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 14:15:56

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US3542053
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
Data entry locked.	System	21 Sep 2020 14:15:56
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 14:15:56

US3542053
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 08:13:30
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 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-21T10:39:46', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '77f9262c-e721-4450-8d5b-d25e90b4f6e0'	System	21 Sep 2020 14:40:04
User entered 'None (1)'	System	21 Sep 2020 14:40:04

FDA-CBER-2022-1614-2660519

US3542053
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 08:13:30
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-21T10:39:49', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '77f9262c-e721-4450-8d5b-d25e90b4f6e0'	System	21 Sep 2020 14:40:04
User entered 'No (N)'	System	21 Sep 2020 14:40:04

FDA-CBER-2022-1614-2660520

US3542053
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 08:13:30
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-21T10:39:53', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '77f9262c-e721-4450-8d5b-d25e90b4f6e0'	System	21 Sep 2020 14:40:04
User entered 'No (N)'	System	21 Sep 2020 14:40:04

FDA-CBER-2022-1614-2660521

US3542053
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 08:13:30
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 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-21T10:39:56', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '77f9262c-e721-4450-8d5b-d25e90b4f6e0'	System	21 Sep 2020 14:40:04
User entered 'None (1)'	System	21 Sep 2020 14:40:04

FDA-CBER-2022-1614-2660522

US3542053
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 08:13:30
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-21T10:40:00', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '77f9262c-e721-4450-8d5b-d25e90b4f6e0'	System	21 Sep 2020 14:40:04
User entered '21 Sep 2020 10:40'	System	21 Sep 2020 14:40:04

US3542053
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 08:13:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '21 Sep 2020 10:24'	System	21 Sep 2020 14:15:56

FDA-CBER-2022-1614-2660524

US3542053
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 08:13:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '21 Sep 2020 12:54'	System	21 Sep 2020 14:15:56

US3542053
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
Data entry locked.	System	21 Sep 2020 14:15:56
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 14:15:56

US3542053
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 08:13:30
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 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-21T21:31:12', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '2403504f-d9e4-45df-a531-5df2e8c5f162'	System	22 Sep 2020 01:32:08
User entered 'None (1)'	System	22 Sep 2020 01:32:08

FDA-CBER-2022-1614-2660527

US3542053
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 08:13:30
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-21T21:31:15', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '2403504f-d9e4-45df-a531-5df2e8c5f162'	System	22 Sep 2020 01:32:08
User entered 'No (N)'	System	22 Sep 2020 01:32:08

FDA-CBER-2022-1614-2660528

US3542053
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 08:13:30
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-21T21:31:19', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '2403504f-d9e4-45df-a531-5df2e8c5f162'	System	22 Sep 2020 01:32:08
User entered 'No (N)'	System	22 Sep 2020 01:32:08

FDA-CBER-2022-1614-2660529

US3542053
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 08:13:30
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 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-21T21:31:23', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '2403504f-d9e4-45df-a531-5df2e8c5f162'	System	22 Sep 2020 01:32:08
User entered 'None (1)'	System	22 Sep 2020 01:32:08

US3542053
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 08:13:30
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-21T21:32:06', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '2403504f-d9e4-45df-a531-5df2e8c5f162'	System	22 Sep 2020 01:32:08
User entered '21 Sep 2020 21:32'	System	22 Sep 2020 01:32:08

FDA-CBER-2022-1614-2660531

US3542053
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 08:13:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '21 Sep 2020 13:49'	System	21 Sep 2020 14:15:56

FDA-CBER-2022-1614-2660532

US3542053
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 08:13:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 14:15:56

FDA-CBER-2022-1614-2660533

US3542053
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
Data entry locked.	System	21 Sep 2020 14:15:56
User entered 'Day 2'	System	21 Sep 2020 14:15:56

FDA-CBER-2022-1614-2660534

US3542053
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 08:13:30
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 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-22T21:53:51', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '4bd08c96-c828-4c87-b175-0f78f28108a2'	System	23 Sep 2020 01:54:17
User entered 'None (1)'	System	23 Sep 2020 01:54:17

FDA-CBER-2022-1614-2660535

US3542053
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 08:13:30
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-22T21:53:55', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '4bd08c96-c828-4c87-b175-0f78f28108a2'	System	23 Sep 2020 01:54:17
User entered 'No (N)'	System	23 Sep 2020 01:54:17

FDA-CBER-2022-1614-2660536

US3542053
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 08:13:30
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-22T21:53:59', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '4bd08c96-c828-4c87-b175-0f78f28108a2'	System	23 Sep 2020 01:54:17
User entered 'No (N)'	System	23 Sep 2020 01:54:17

FDA-CBER-2022-1614-2660537

US3542053
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 08:13:30
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 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-22T21:54:04', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '4bd08c96-c828-4c87-b175-0f78f28108a2'	System	23 Sep 2020 01:54:17
User entered 'None (1)'	System	23 Sep 2020 01:54:17

FDA-CBER-2022-1614-2660538

US3542053
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 08:13:30
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-22T21:54:15', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '4bd08c96-c828-4c87-b175-0f78f28108a2'	System	23 Sep 2020 01:54:17
User entered '22 Sep 2020 21:54'	System	23 Sep 2020 01:54:17

US3542053
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 08:13:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 14:15:56

FDA-CBER-2022-1614-2660540

US3542053
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 08:13:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 14:15:56

FDA-CBER-2022-1614-2660541

US3542053
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
Data entry locked.	System	21 Sep 2020 14:15:56
User entered 'Day 3'	System	21 Sep 2020 14:15:56

FDA-CBER-2022-1614-2660542

US3542053
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 08:13:30
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 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-23T21:38:29', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '0a824e73-d70b-4618-9fcc-fbcdb939b834'	System	24 Sep 2020 01:38:49
User entered 'None (1)'	System	24 Sep 2020 01:38:49

FDA-CBER-2022-1614-2660543

US3542053
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 08:13:30
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-23T21:38:35', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '0a824e73-d70b-4618-9fcc-fbcdb939b834'	System	24 Sep 2020 01:38:49
User entered 'No (N)'	System	24 Sep 2020 01:38:49

FDA-CBER-2022-1614-2660544

US3542053
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 08:13:30
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-23T21:38:38', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '0a824e73-d70b-4618-9fcc-fbcdb939b834'	System	24 Sep 2020 01:38:49
User entered 'No (N)'	System	24 Sep 2020 01:38:49

FDA-CBER-2022-1614-2660545

US3542053
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 08:13:30
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 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-23T21:38:43', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '0a824e73-d70b-4618-9fcc-fbcdb939b834'	System	24 Sep 2020 01:38:49
User entered 'None (1)'	System	24 Sep 2020 01:38:49

FDA-CBER-2022-1614-2660546

US3542053
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 08:13:30
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-23T21:38:47', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '0a824e73-d70b-4618-9fcc-fbcdb939b834'	System	24 Sep 2020 01:38:49
User entered '23 Sep 2020 21:38'	System	24 Sep 2020 01:38:49

FDA-CBER-2022-1614-2660547

US3542053
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 08:13:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 14:15:56

FDA-CBER-2022-1614-2660548

US3542053
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 08:13:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 14:15:56

FDA-CBER-2022-1614-2660549

US3542053
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
Data entry locked.	System	21 Sep 2020 14:15:56
User entered 'Day 4'	System	21 Sep 2020 14:15:56

FDA-CBER-2022-1614-2660550

US3542053
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 08:13:30
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 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-24T22:00:07', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '9a615e61-fa1f-4fe3-a5c6-bdea26581bb1'	System	25 Sep 2020 02:00:43
User entered 'None (1)'	System	25 Sep 2020 02:00:43

FDA-CBER-2022-1614-2660551

US3542053
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 08:13:30
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-24T22:00:11', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '9a615e61-fa1f-4fe3-a5c6-bdea26581bb1'	System	25 Sep 2020 02:00:43
User entered 'No (N)'	System	25 Sep 2020 02:00:43

US3542053
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 08:13:30
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-24T22:00:16', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '9a615e61-fa1f-4fe3-a5c6-bdea26581bb1'	System	25 Sep 2020 02:00:43
User entered 'No (N)'	System	25 Sep 2020 02:00:43

US3542053
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 08:13:30
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 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-24T22:00:17', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '9a615e61-fa1f-4fe3-a5c6-bdea26581bb1'	System	25 Sep 2020 02:00:43
User entered 'None (1)'	System	25 Sep 2020 02:00:43

FDA-CBER-2022-1614-2660554

US3542053
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 08:13:30
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-24T22:00:22', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '9a615e61-fa1f-4fe3-a5c6-bdea26581bb1'	System	25 Sep 2020 02:00:43
User entered '24 Sep 2020 22:00'	System	25 Sep 2020 02:00:43

US3542053
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 08:13:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 14:15:56

FDA-CBER-2022-1614-2660556

US3542053
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 08:13:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 14:15:56

FDA-CBER-2022-1614-2660557

US3542053
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
Data entry locked.	System	21 Sep 2020 14:15:56
User entered 'Day 5'	System	21 Sep 2020 14:15:56

FDA-CBER-2022-1614-2660558

US3542053
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 08:13:30
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 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-25T20:59:10', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'dd2ada1c-1cae-4ba3-8da5-244f558b317d'	System	26 Sep 2020 00:59:55
User entered 'None (1)'	System	26 Sep 2020 00:59:55

FDA-CBER-2022-1614-2660559

US3542053
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 08:13:30
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-25T20:59:16', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'dd2ada1c-1cae-4ba3-8da5-244f558b317d'	System	26 Sep 2020 00:59:55
User entered 'No (N)'	System	26 Sep 2020 00:59:55

US3542053
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 08:13:30
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-25T20:59:20', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'dd2ada1c-1cae-4ba3-8da5-244f558b317d'	System	26 Sep 2020 00:59:55
User entered 'No (N)'	System	26 Sep 2020 00:59:55

FDA-CBER-2022-1614-2660561

US3542053
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 08:13:30
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 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-25T20:59:25', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'dd2ada1c-1cae-4ba3-8da5-244f558b317d'	System	26 Sep 2020 00:59:55
User entered 'None (1)'	System	26 Sep 2020 00:59:55

FDA-CBER-2022-1614-2660562

US3542053
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 08:13:30
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-25T20:59:50', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'dd2ada1c-1cae-4ba3-8da5-244f558b317d'	System	26 Sep 2020 00:59:55
User entered '25 Sep 2020 20:59'	System	26 Sep 2020 00:59:55

US3542053
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 08:13:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 14:15:56

FDA-CBER-2022-1614-2660564

US3542053
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 08:13:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 14:15:56

FDA-CBER-2022-1614-2660565

US3542053
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
Data entry locked.	System	21 Sep 2020 14:15:56
User entered 'Day 6'	System	21 Sep 2020 14:15:56

FDA-CBER-2022-1614-2660566

US3542053
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 08:13:30
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 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-26T22:05:31', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '68bd36df-9951-4614-80ca-299fb4513c48'	System	27 Sep 2020 02:05:48
User entered 'None (1)'	System	27 Sep 2020 02:05:48

FDA-CBER-2022-1614-2660567

US3542053
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 08:13:30
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-26T22:05:34', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '68bd36df-9951-4614-80ca-299fb4513c48'	System	27 Sep 2020 02:05:48
User entered 'No (N)'	System	27 Sep 2020 02:05:48

FDA-CBER-2022-1614-2660568

US3542053
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 08:13:30
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-26T22:05:39', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '68bd36df-9951-4614-80ca-299fb4513c48'	System	27 Sep 2020 02:05:48
User entered 'No (N)'	System	27 Sep 2020 02:05:48

FDA-CBER-2022-1614-2660569

US3542053
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 08:13:30
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 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-26T22:05:43', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '68bd36df-9951-4614-80ca-299fb4513c48'	System	27 Sep 2020 02:05:48
User entered 'None (1)'	System	27 Sep 2020 02:05:48

FDA-CBER-2022-1614-2660570

US3542053
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 08:13:30
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-26T22:05:46', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '68bd36df-9951-4614-80ca-299fb4513c48'	System	27 Sep 2020 02:05:48
User entered '26 Sep 2020 22:05'	System	27 Sep 2020 02:05:48

FDA-CBER-2022-1614-2660571

US3542053
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 08:13:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 14:15:56

FDA-CBER-2022-1614-2660572

US3542053
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 08:13:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 14:15:56

FDA-CBER-2022-1614-2660573

US3542053
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
Data entry locked.	System	21 Sep 2020 14:15:56
User entered 'Day 7'	System	21 Sep 2020 14:15:56

FDA-CBER-2022-1614-2660574

US3542053
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 08:13:30
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 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-28T00:02:22', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '080d151d-fe27-41d7-ba54-be787997ac7e'	System	28 Sep 2020 04:02:41
User entered 'None (1)'	System	28 Sep 2020 04:02:41

FDA-CBER-2022-1614-2660575

US3542053
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 08:13:30
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-28T00:02:25', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '080d151d-fe27-41d7-ba54-be787997ac7e'	System	28 Sep 2020 04:02:41
User entered 'No (N)'	System	28 Sep 2020 04:02:41

FDA-CBER-2022-1614-2660576

US3542053
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 08:13:30
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-28T00:02:29', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '080d151d-fe27-41d7-ba54-be787997ac7e'	System	28 Sep 2020 04:02:41
User entered 'No (N)'	System	28 Sep 2020 04:02:41

FDA-CBER-2022-1614-2660577

US3542053
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 08:13:30
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 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-28T00:02:33', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '080d151d-fe27-41d7-ba54-be787997ac7e'	System	28 Sep 2020 04:02:41
User entered 'None (1)'	System	28 Sep 2020 04:02:41

FDA-CBER-2022-1614-2660578

US3542053
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 08:13:30
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-28T00:02:37', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '080d151d-fe27-41d7-ba54-be787997ac7e'	System	28 Sep 2020 04:02:41
User entered '28 Sep 2020 00:02'	System	28 Sep 2020 04:02:41

FDA-CBER-2022-1614-2660579

US3542053
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 08:13:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 14:15:56

FDA-CBER-2022-1614-2660580

US3542053
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 08:13:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 14:15:56

FDA-CBER-2022-1614-2660581

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
Data entry locked.	System	21 Sep 2020 14:15:56
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 14:15:56

FDA-CBER-2022-1614-2660582

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 08:13:30
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-21T10:40:05', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '89961d27-4068-4d2f-8c86-64aa423c3084'	System	21 Sep 2020 14:40:30
User entered 'None (0)'	System	21 Sep 2020 14:40:30

FDA-CBER-2022-1614-2660583

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 08:13:30
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-21T10:40:07', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '89961d27-4068-4d2f-8c86-64aa423c3084'	System	21 Sep 2020 14:40:30
User entered 'None (0)'	System	21 Sep 2020 14:40:30

FDA-CBER-2022-1614-2660584

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 08:13:30
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-21T10:40:09', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '89961d27-4068-4d2f-8c86-64aa423c3084'	System	21 Sep 2020 14:40:30
User entered 'None (0)'	System	21 Sep 2020 14:40:30

FDA-CBER-2022-1614-2660585

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 08:13:30
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-21T10:40:12', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '89961d27-4068-4d2f-8c86-64aa423c3084'	System	21 Sep 2020 14:40:30
User entered 'None (0)'	System	21 Sep 2020 14:40:30

FDA-CBER-2022-1614-2660586

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 08:13:30
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-21T10:40:14', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '89961d27-4068-4d2f-8c86-64aa423c3084'	System	21 Sep 2020 14:40:30
User entered 'None (0)'	System	21 Sep 2020 14:40:30

FDA-CBER-2022-1614-2660587

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 08:13:30
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-21T10:40:16', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '89961d27-4068-4d2f-8c86-64aa423c3084'	System	21 Sep 2020 14:40:30
User entered 'None (0)'	System	21 Sep 2020 14:40:30

FDA-CBER-2022-1614-2660588

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 08:13:30
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-21T10:40:21', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '89961d27-4068-4d2f-8c86-64aa423c3084'	System	21 Sep 2020 14:40:30
User entered 'No (N)'	System	21 Sep 2020 14:40:30

FDA-CBER-2022-1614-2660589

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 08:13:30
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-21T10:40:27', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '89961d27-4068-4d2f-8c86-64aa423c3084'	System	21 Sep 2020 14:40:30
User entered '21 Sep 2020 10:40'	System	21 Sep 2020 14:40:30

FDA-CBER-2022-1614-2660590

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 08:13:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '21 Sep 2020 10:24'	System	21 Sep 2020 14:15:56

FDA-CBER-2022-1614-2660591

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 08:13:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '21 Sep 2020 12:54'	System	21 Sep 2020 14:15:56

FDA-CBER-2022-1614-2660592

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
Data entry locked.	System	21 Sep 2020 14:15:56
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 14:15:56

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 08:13:30
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-21T21:32:51', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '99ed1702-d7f9-4f4b-992e-de6e6fca57bf'	System	22 Sep 2020 01:33:30
User entered 'None (0)'	System	22 Sep 2020 01:33:30

FDA-CBER-2022-1614-2660594

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 08:13:30
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-21T21:32:55', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '99ed1702-d7f9-4f4b-992e-de6e6fca57bf'	System	22 Sep 2020 01:33:30
User entered 'None (0)'	System	22 Sep 2020 01:33:30

FDA-CBER-2022-1614-2660595

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 08:13:30
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-21T21:32:58', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '99ed1702-d7f9-4f4b-992e-de6e6fca57bf'	System	22 Sep 2020 01:33:30
User entered 'None (0)'	System	22 Sep 2020 01:33:30

FDA-CBER-2022-1614-2660596

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 08:13:30
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-21T21:33:02', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '99ed1702-d7f9-4f4b-992e-de6e6fca57bf'	System	22 Sep 2020 01:33:30
User entered 'None (0)'	System	22 Sep 2020 01:33:30

FDA-CBER-2022-1614-2660597

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 08:13:30
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-21T21:33:05', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '99ed1702-d7f9-4f4b-992e-de6e6fca57bf'	System	22 Sep 2020 01:33:30
User entered 'None (0)'	System	22 Sep 2020 01:33:30

FDA-CBER-2022-1614-2660598

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 08:13:30
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-21T21:33:07', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '99ed1702-d7f9-4f4b-992e-de6e6fca57bf'	System	22 Sep 2020 01:33:30
User entered 'None (0)'	System	22 Sep 2020 01:33:30

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 08:13:30
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-21T21:33:16', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '99ed1702-d7f9-4f4b-992e-de6e6fca57bf'	System	22 Sep 2020 01:33:30
User entered 'No (N)'	System	22 Sep 2020 01:33:30

FDA-CBER-2022-1614-2660600

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 08:13:30
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-21T21:33:29', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '99ed1702-d7f9-4f4b-992e-de6e6fca57bf'	System	22 Sep 2020 01:33:30
User entered '21 Sep 2020 21:33'	System	22 Sep 2020 01:33:30

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 08:13:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '21 Sep 2020 13:49'	System	21 Sep 2020 14:15:56

FDA-CBER-2022-1614-2660602

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 08:13:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 14:15:56

FDA-CBER-2022-1614-2660603

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
Data entry locked.	System	21 Sep 2020 14:15:56
User entered 'Day 2'	System	21 Sep 2020 14:15:56

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 08:13:30
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-22T21:54:20', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '2c6dd80f-a70a-4ca6-a1a7-9b35a8de0cca'	System	23 Sep 2020 01:54:56
User entered 'None (0)'	System	23 Sep 2020 01:54:56

FDA-CBER-2022-1614-2660605

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 08:13:30
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-22T21:54:23', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '2c6dd80f-a70a-4ca6-a1a7-9b35a8de0cca'	System	23 Sep 2020 01:54:56
User entered 'None (0)'	System	23 Sep 2020 01:54:56

FDA-CBER-2022-1614-2660606

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 08:13:30
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-22T21:54:27', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '2c6dd80f-a70a-4ca6-a1a7-9b35a8de0cca'	System	23 Sep 2020 01:54:56
User entered 'None (0)'	System	23 Sep 2020 01:54:56

FDA-CBER-2022-1614-2660607

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 08:13:30
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-22T21:54:30', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '2c6dd80f-a70a-4ca6-a1a7-9b35a8de0cca'	System	23 Sep 2020 01:54:56
User entered 'None (0)'	System	23 Sep 2020 01:54:56

FDA-CBER-2022-1614-2660608

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 08:13:30
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-22T21:54:33', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '2c6dd80f-a70a-4ca6-a1a7-9b35a8de0cca'	System	23 Sep 2020 01:54:56
User entered 'None (0)'	System	23 Sep 2020 01:54:56

FDA-CBER-2022-1614-2660609

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 08:13:30
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-22T21:54:36', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '2c6dd80f-a70a-4ca6-a1a7-9b35a8de0cca'	System	23 Sep 2020 01:54:56
User entered 'None (0)'	System	23 Sep 2020 01:54:56

FDA-CBER-2022-1614-2660610

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 08:13:30
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-22T21:54:51', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '2c6dd80f-a70a-4ca6-a1a7-9b35a8de0cca'	System	23 Sep 2020 01:54:56
User entered 'No (N)'	System	23 Sep 2020 01:54:56

FDA-CBER-2022-1614-2660611

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 08:13:30
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-22T21:54:54', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '2c6dd80f-a70a-4ca6-a1a7-9b35a8de0cca'	System	23 Sep 2020 01:54:56
User entered '22 Sep 2020 21:54'	System	23 Sep 2020 01:54:56

FDA-CBER-2022-1614-2660612

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 08:13:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 14:15:56

FDA-CBER-2022-1614-2660613

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 08:13:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 14:15:56

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
Data entry locked.	System	21 Sep 2020 14:15:56
User entered 'Day 3'	System	21 Sep 2020 14:15:56

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 08:13:30
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-23T21:38:52', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '4118b7cf-6c6e-4162-b262-4d0394fef8d3'	System	24 Sep 2020 01:39:20
User entered 'None (0)'	System	24 Sep 2020 01:39:20

FDA-CBER-2022-1614-2660616

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 08:13:30
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-23T21:38:55', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '4118b7cf-6c6e-4162-b262-4d0394fef8d3'	System	24 Sep 2020 01:39:20
User entered 'None (0)'	System	24 Sep 2020 01:39:20

FDA-CBER-2022-1614-2660617

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 08:13:30
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-23T21:38:58', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '4118b7cf-6c6e-4162-b262-4d0394fef8d3'	System	24 Sep 2020 01:39:20
User entered 'None (0)'	System	24 Sep 2020 01:39:20

FDA-CBER-2022-1614-2660618

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 08:13:30
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-23T21:39:02', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '4118b7cf-6c6e-4162-b262-4d0394fef8d3'	System	24 Sep 2020 01:39:20
User entered 'None (0)'	System	24 Sep 2020 01:39:20

FDA-CBER-2022-1614-2660619

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 08:13:30
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-23T21:39:04', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '4118b7cf-6c6e-4162-b262-4d0394fef8d3'	System	24 Sep 2020 01:39:20
User entered 'None (0)'	System	24 Sep 2020 01:39:20

FDA-CBER-2022-1614-2660620

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 08:13:30
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-23T21:39:07', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '4118b7cf-6c6e-4162-b262-4d0394fef8d3'	System	24 Sep 2020 01:39:20
User entered 'None (0)'	System	24 Sep 2020 01:39:20

FDA-CBER-2022-1614-2660621

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 08:13:30
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-23T21:39:11', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '4118b7cf-6c6e-4162-b262-4d0394fef8d3'	System	24 Sep 2020 01:39:20
User entered 'No (N)'	System	24 Sep 2020 01:39:20

FDA-CBER-2022-1614-2660622

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 08:13:30
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-23T21:39:17', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '4118b7cf-6c6e-4162-b262-4d0394fef8d3'	System	24 Sep 2020 01:39:20
User entered '23 Sep 2020 21:39'	System	24 Sep 2020 01:39:20

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 08:13:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 14:15:56

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 08:13:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 14:15:56

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
Data entry locked.	System	21 Sep 2020 14:15:56
User entered 'Day 4'	System	21 Sep 2020 14:15:56

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 08:13:30
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-24T22:00:27', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '894cd5c1-3595-4a3c-bd66-cb61ffafaf32'	System	25 Sep 2020 02:00:55
User entered 'None (0)'	System	25 Sep 2020 02:00:55

FDA-CBER-2022-1614-2660627

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 08:13:30
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-24T22:00:30', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '894cd5c1-3595-4a3c-bd66-cb61ffafaf32'	System	25 Sep 2020 02:00:55
User entered 'None (0)'	System	25 Sep 2020 02:00:55

FDA-CBER-2022-1614-2660628

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 08:13:30
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-24T22:00:34', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '894cd5c1-3595-4a3c-bd66-cb61ffafaf32'	System	25 Sep 2020 02:00:55
User entered 'None (0)'	System	25 Sep 2020 02:00:55

FDA-CBER-2022-1614-2660629

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 08:13:30
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-24T22:00:38', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '894cd5c1-3595-4a3c-bd66-cb61ffafaf32'	System	25 Sep 2020 02:00:55
User entered 'None (0)'	System	25 Sep 2020 02:00:55

FDA-CBER-2022-1614-2660630

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 08:13:30
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-24T22:00:41', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '894cd5c1-3595-4a3c-bd66-cb61ffafaf32'	System	25 Sep 2020 02:00:55
User entered 'None (0)'	System	25 Sep 2020 02:00:55

FDA-CBER-2022-1614-2660631

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 08:13:30
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-24T22:00:43', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '894cd5c1-3595-4a3c-bd66-cb61ffafaf32'	System	25 Sep 2020 02:00:55
User entered 'None (0)'	System	25 Sep 2020 02:00:55

FDA-CBER-2022-1614-2660632

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 08:13:30
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-24T22:00:47', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '894cd5c1-3595-4a3c-bd66-cb61ffafaf32'	System	25 Sep 2020 02:00:55
User entered 'No (N)'	System	25 Sep 2020 02:00:55

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 08:13:30
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-24T22:00:51', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '894cd5c1-3595-4a3c-bd66-cb61ffafaf32'	System	25 Sep 2020 02:00:55
User entered '24 Sep 2020 22:00'	System	25 Sep 2020 02:00:55

FDA-CBER-2022-1614-2660634

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 08:13:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 14:15:56

FDA-CBER-2022-1614-2660635

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 08:13:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 14:15:56

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
Data entry locked.	System	21 Sep 2020 14:15:56
User entered 'Day 5'	System	21 Sep 2020 14:15:56

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 08:13:30
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-25T21:00:12', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '8314642a-6d27-4ac5-985a-bb05fa87f3d1'	System	26 Sep 2020 01:10:37
User entered 'None (0)'	System	26 Sep 2020 01:10:37

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 08:13:30
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-25T21:00:17', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '8314642a-6d27-4ac5-985a-bb05fa87f3d1'	System	26 Sep 2020 01:10:37
User entered 'None (0)'	System	26 Sep 2020 01:10:37

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 08:13:30
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-25T21:00:44', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '8314642a-6d27-4ac5-985a-bb05fa87f3d1'	System	26 Sep 2020 01:10:37
User entered 'Some interference with activity (2)'	System	26 Sep 2020 01:10:37

FDA-CBER-2022-1614-2660640

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 08:13:30
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-25T21:02:12', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '8314642a-6d27-4ac5-985a-bb05fa87f3d1'	System	26 Sep 2020 01:10:37
User entered 'Some interference with activity (2)'	System	26 Sep 2020 01:10:37

FDA-CBER-2022-1614-2660641

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 08:13:30
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-25T21:01:16', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '8314642a-6d27-4ac5-985a-bb05fa87f3d1'	System	26 Sep 2020 01:10:37
User entered 'None (0)'	System	26 Sep 2020 01:10:37

FDA-CBER-2022-1614-2660642

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 08:13:30
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-25T21:01:20', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '8314642a-6d27-4ac5-985a-bb05fa87f3d1'	System	26 Sep 2020 01:10:37
User entered 'None (0)'	System	26 Sep 2020 01:10:37

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 08:13:30
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-25T21:01:30', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '8314642a-6d27-4ac5-985a-bb05fa87f3d1'	System	26 Sep 2020 01:10:37
User entered 'No (N)'	System	26 Sep 2020 01:10:37

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 08:13:30
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-25T21:02:18', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '8314642a-6d27-4ac5-985a-bb05fa87f3d1'	System	26 Sep 2020 01:10:37
User entered '25 Sep 2020 21:02'	System	26 Sep 2020 01:10:37

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 08:13:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 14:15:56

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 08:13:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 14:15:56

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
Data entry locked.	System	21 Sep 2020 14:15:56
User entered 'Day 6'	System	21 Sep 2020 14:15:56

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 08:13:30
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-26T22:05:51', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'fde2b327-6c8d-416e-a476-eb92472353bd'	System	27 Sep 2020 02:06:53
User entered 'None (0)'	System	27 Sep 2020 02:06:53

FDA-CBER-2022-1614-2660649

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 08:13:30
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-26T22:05:54', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'fde2b327-6c8d-416e-a476-eb92472353bd'	System	27 Sep 2020 02:06:53
User entered 'None (0)'	System	27 Sep 2020 02:06:53

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 08:13:30
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-26T22:06:09', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'fde2b327-6c8d-416e-a476-eb92472353bd'	System	27 Sep 2020 02:06:53
User entered 'Significant; prevents daily activity (3)'	System	27 Sep 2020 02:06:53

FDA-CBER-2022-1614-2660651

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 08:13:30
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-26T22:06:16', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'fde2b327-6c8d-416e-a476-eb92472353bd'	System	27 Sep 2020 02:06:53
User entered 'None (0)'	System	27 Sep 2020 02:06:53

FDA-CBER-2022-1614-2660652

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 08:13:30
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-26T22:06:20', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'fde2b327-6c8d-416e-a476-eb92472353bd'	System	27 Sep 2020 02:06:53
User entered 'None (0)'	System	27 Sep 2020 02:06:53

FDA-CBER-2022-1614-2660653

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 08:13:30
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-26T22:06:23', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'fde2b327-6c8d-416e-a476-eb92472353bd'	System	27 Sep 2020 02:06:53
User entered 'None (0)'	System	27 Sep 2020 02:06:53

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 08:13:30
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-26T22:06:28', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'fde2b327-6c8d-416e-a476-eb92472353bd'	System	27 Sep 2020 02:06:53
User entered 'Yes (Y)'	System	27 Sep 2020 02:06:53

FDA-CBER-2022-1614-2660655

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 08:13:30
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-26T22:06:50', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'fde2b327-6c8d-416e-a476-eb92472353bd'	System	27 Sep 2020 02:06:53
User entered '26 Sep 2020 22:06'	System	27 Sep 2020 02:06:53

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 08:13:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 14:15:56

FDA-CBER-2022-1614-2660657

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 08:13:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 14:15:56

FDA-CBER-2022-1614-2660658

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
Data entry locked.	System	21 Sep 2020 14:15:56
User entered 'Day 7'	System	21 Sep 2020 14:15:56

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 08:13:30
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-28T00:02:42', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'e4d1557a-bf57-4068-9bc3-b4943a766c53'	System	28 Sep 2020 04:03:30
User entered 'None (0)'	System	28 Sep 2020 04:03:30

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 08:13:30
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-28T00:02:45', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'e4d1557a-bf57-4068-9bc3-b4943a766c53'	System	28 Sep 2020 04:03:30
User entered 'None (0)'	System	28 Sep 2020 04:03:30

FDA-CBER-2022-1614-2660661

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 08:13:30
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-28T00:03:23', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'e4d1557a-bf57-4068-9bc3-b4943a766c53'	System	28 Sep 2020 04:03:30
User entered 'No interference with activity (1)'	System	28 Sep 2020 04:03:30

FDA-CBER-2022-1614-2660662

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 08:13:30
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-28T00:02:55', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'e4d1557a-bf57-4068-9bc3-b4943a766c53'	System	28 Sep 2020 04:03:30
User entered 'None (0)'	System	28 Sep 2020 04:03:30

FDA-CBER-2022-1614-2660663

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 08:13:30
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-28T00:02:57', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'e4d1557a-bf57-4068-9bc3-b4943a766c53'	System	28 Sep 2020 04:03:30
User entered 'None (0)'	System	28 Sep 2020 04:03:30

FDA-CBER-2022-1614-2660664

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 08:13:30
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-28T00:03:00', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'e4d1557a-bf57-4068-9bc3-b4943a766c53'	System	28 Sep 2020 04:03:30
User entered 'None (0)'	System	28 Sep 2020 04:03:30

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 08:13:30
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-28T00:03:09', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'e4d1557a-bf57-4068-9bc3-b4943a766c53'	System	28 Sep 2020 04:03:30
User entered 'No (N)'	System	28 Sep 2020 04:03:30

FDA-CBER-2022-1614-2660666

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 08:13:30
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-28T00:03:27', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'e4d1557a-bf57-4068-9bc3-b4943a766c53'	System	28 Sep 2020 04:03:30
User entered '28 Sep 2020 00:03'	System	28 Sep 2020 04:03:30

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 08:13:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 14:15:56

US3542053
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 08:13:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 14:15:56

US3542053
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(8)
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
Data entry locked.	System	27 Sep 2020 02:06:53
User entered 'Day 8'	System	27 Sep 2020 02:06:53

FDA-CBER-2022-1614-2660670

US3542053
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(8)
Generated On: 10 Jun 2021 08:13:30
Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49

US3542053
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(8)
Generated On: 10 Jun 2021 08:13:30
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49

FDA-CBER-2022-1614-2660672

US3542053
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(8)
Generated On: 10 Jun 2021 08:13:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '28 Sep 2020 12:00'	System	27 Sep 2020 02:06:53

FDA-CBER-2022-1614-2660673

US3542053
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(8)
Generated On: 10 Jun 2021 08:13:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '29 Sep 2020 11:59'	System	27 Sep 2020 02:06:53

FDA-CBER-2022-1614-2660674

US3542053
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(9)
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
Data entry locked.	System	28 Sep 2020 04:03:30
User entered 'Day 9'	System	28 Sep 2020 04:03:30

US3542053
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(9)
Generated On: 10 Jun 2021 08:13:30
Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-29T22:48:59', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'c5c30d35-6ec9-44b7-abb8-d288b524fb76'	System	30 Sep 2020 02:49:10
User entered 'None (0)'	System	30 Sep 2020 02:49:10

FDA-CBER-2022-1614-2660676

US3542053
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(9)
Generated On: 10 Jun 2021 08:13:30
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-29T22:49:05', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'c5c30d35-6ec9-44b7-abb8-d288b524fb76'	System	30 Sep 2020 02:49:10
User entered '29 Sep 2020 22:49'	System	30 Sep 2020 02:49:10

FDA-CBER-2022-1614-2660677

US3542053
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(9)
Generated On: 10 Jun 2021 08:13:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '29 Sep 2020 12:00'	System	28 Sep 2020 04:03:30

FDA-CBER-2022-1614-2660678

US3542053
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(9)
Generated On: 10 Jun 2021 08:13:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '30 Sep 2020 11:59'	System	28 Sep 2020 04:03:30

US3542053
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(8)
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
Data entry locked.	System	27 Sep 2020 02:05:29
User entered 'Day 8'	System	27 Sep 2020 02:05:29

US3542053
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(8)
Generated On: 10 Jun 2021 08:13:30
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49

FDA-CBER-2022-1614-2660681

US3542053
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(8)
Generated On: 10 Jun 2021 08:13:30
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49

FDA-CBER-2022-1614-2660682

US3542053
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(8)
Generated On: 10 Jun 2021 08:13:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '28 Sep 2020 12:00'	System	27 Sep 2020 02:05:29

FDA-CBER-2022-1614-2660683

US3542053
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(8)
Generated On: 10 Jun 2021 08:13:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '29 Sep 2020 11:59'	System	27 Sep 2020 02:05:29

US3542053
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(9)
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
Data entry locked.	System	28 Sep 2020 04:03:30
User entered 'Day 9'	System	28 Sep 2020 04:03:30

FDA-CBER-2022-1614-2660685

US3542053
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(9)
Generated On: 10 Jun 2021 08:13:30
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-29T22:49:13', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'b5c9dfeb-d232-4345-b89d-87bb58d9fd42'	System	30 Sep 2020 02:49:21
User entered 'No (N)'	System	30 Sep 2020 02:49:21

FDA-CBER-2022-1614-2660686

US3542053
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(9)
Generated On: 10 Jun 2021 08:13:30
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-09-29T22:49:17', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'b5c9dfeb-d232-4345-b89d-87bb58d9fd42'	System	30 Sep 2020 02:49:21
User entered '29 Sep 2020 22:49'	System	30 Sep 2020 02:49:21

FDA-CBER-2022-1614-2660687

US3542053
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(9)
Generated On: 10 Jun 2021 08:13:30
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '29 Sep 2020 12:00'	System	28 Sep 2020 04:03:30

FDA-CBER-2022-1614-2660688

US3542053
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(9)
Generated On: 10 Jun 2021 08:13:30
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
User entered '30 Sep 2020 11:59'	System	28 Sep 2020 04:03:30

FDA-CBER-2022-1614-2660689

US3542053
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 10 Jun 2021 08:13:30
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	30 Sep 2020 22:38:17
User entered 'Yes (Y)'	DeEnna Wedding (b) (4) (b) (4)	30 Sep 2020 18:32:32

US3542053
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 10 Jun 2021 08:13:30
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	30 Sep 2020 22:38:17
User entered '29 Sep 2020'	DeEnna Wedding (b) (4) (b) (4)	30 Sep 2020 18:32:32

US3542053
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 10 Jun 2021 08:13:30
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	30 Sep 2020 22:38:17
User entered 'Contact Made (CONTACT MADE)'	DeEnna Wedding (b) (4) (b) (4)	30 Sep 2020 18:32:32

US3542053
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 10 Jun 2021 08:13:30
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	30 Sep 2020 22:38:17
User entered empty.	DeEnna Wedding (b) (4) (b) (4)	30 Sep 2020 18:32:32

FDA-CBER-2022-1614-2660693

US3542053
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 10 Jun 2021 08:13:30
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	30 Sep 2020 22:38:17
User entered 'Yes (Y)'	DeEnna Wedding (b) (4) (b) (4)	30 Sep 2020 18:32:18

US3542053
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 10 Jun 2021 08:13:30
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User entered '1'	System	30 Sep 2020 18:32:18

FDA-CBER-2022-1614-2660695

US3542053
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 10 Jun 2021 08:13:30
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:55:32
User entered 'Yes (Y)'	(b) (4) Madhu Balachandran (b) (4)	07 Oct 2020 18:09:18

FDA-CBER-2022-1614-2660696

US3542053
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 10 Jun 2021 08:13:30
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:55:32
User entered '6 Oct 2020'	Madhu Balachandran (b) (4)	07 Oct 2020 18:09:18

US3542053
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 10 Jun 2021 08:13:30
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:55:32
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Madhu Balachandran (b) (4)	07 Oct 2020 18:09:18

FDA-CBER-2022-1614-2660698

US3542053
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 10 Jun 2021 08:13:30
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	08 Oct 2020 02:55:32
User entered empty.	Madhu Balachandran (b) (4)	07 Oct 2020 18:09:18

US3542053
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 10 Jun 2021 08:13:30
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4)	08 Oct 2020 02:55:32
User entered 'Yes (Y)'	Madhu Balachandran (b) (4)	07 Oct 2020 18:09:25

US3542053
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 10 Jun 2021 08:13:30
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User entered '1'	System	07 Oct 2020 18:09:25

FDA-CBER-2022-1614-2660701

US3542053
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 10 Jun 2021 08:13:30
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Oct 2020 02:46:06
User entered 'Yes (Y)'	Taylor Ladson (b) (4) (b) (4)	15 Oct 2020 13:39:02

FDA-CBER-2022-1614-2660702

US3542053
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 10 Jun 2021 08:13:30
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Oct 2020 02:46:06
User entered '13 Oct 2020'	Taylor Ladson (b) (4) (b) (4)	15 Oct 2020 13:39:02

US3542053
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 10 Jun 2021 08:13:30
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Oct 2020 02:46:06
User entered 'Contact Made (CONTACT MADE)'	Taylor Ladson (b) (4) (b) (4)	15 Oct 2020 13:39:02

US3542053
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 10 Jun 2021 08:13:30
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Oct 2020 02:46:06
User entered empty.	Taylor Ladson (b) (4) (b) (4)	15 Oct 2020 13:39:02

US3542053
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 10 Jun 2021 08:13:30
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Oct 2020 02:46:06
User entered 'Yes (Y)'	Taylor Ladson (b) (4) (b) (4)	15 Oct 2020 13:40:31

FDA-CBER-2022-1614-2660706

US3542053
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 10 Jun 2021 08:13:30
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User entered '1'	System	15 Oct 2020 13:40:31

US3542053
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 10 Jun 2021 08:13:30
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Oct 2020 18:32:30
User entered 'Yes (Y)'	Erika Faust (b) (4) (b) (4)	21 Oct 2020 16:03:59

US3542053
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 10 Jun 2021 08:13:30
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Oct 2020 18:32:30
User entered '21 Oct 2020'	Erika Faust (b) (4) (b) (4)	21 Oct 2020 16:03:59

US3542053
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 10 Jun 2021 08:13:30
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Oct 2020 18:32:30
User entered 'Clinic (Clinic)'	Erika Faust (b) (4) (b) (4)	21 Oct 2020 16:03:59

US3542053
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 10 Jun 2021 08:13:30
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User entered 'VISIT3'	System	21 Oct 2020 16:03:59

FDA-CBER-2022-1614-2660711

US3542053
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 08:13:30
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Oct 2020 18:32:30
User entered 'Yes (Y)'	Erika Faust (b) (4) (b) (4)	21 Oct 2020 16:03:37

US3542053
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 08:13:30
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Oct 2020 18:32:30
User entered '21 Oct 2020'	Erika Faust (b) (4) (b) (4)	21 Oct 2020 16:03:37

US3542053
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 08:13:30
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Oct 2020 18:32:30
User entered '09:07'	Erika Faust (b) (4) (b) (4)	21 Oct 2020 16:03:37

US3542053
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 08:13:30
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User entered '21 Oct 2020 09:07'	System	21 Oct 2020 16:03:37

US3542053
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 08:13:30
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Oct 2020 18:32:30
User entered '98.3' F	Erika Faust (b) (4) (b) (4)	21 Oct 2020 16:03:37

US3542053
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 08:13:30
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Oct 2020 18:32:30
User entered 'Oral (Oral)'	Erika Faust (b) (4) (b) (4)	21 Oct 2020 16:03:37

FDA-CBER-2022-1614-2660717

US3542053
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 08:13:30
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Oct 2020 18:32:30
User entered empty.	Erika Faust (b) (4) (b) (4)	21 Oct 2020 16:03:37

FDA-CBER-2022-1614-2660718

US3542053
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 08:13:30
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Oct 2020 18:32:30
User entered '75'	Erika Faust (b) (4) (b) (4)	21 Oct 2020 16:03:37

US3542053
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 08:13:30
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User entered 'bpm'	System	21 Oct 2020 16:03:37

FDA-CBER-2022-1614-2660720

US3542053
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 08:13:30
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Oct 2020 18:32:30
User entered '14'	Erika Faust (b) (4) (b) (4)	21 Oct 2020 16:03:37

US3542053
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 08:13:30
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User entered 'breaths/min'	System	21 Oct 2020 16:03:37

FDA-CBER-2022-1614-2660722

US3542053
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 08:13:30
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Oct 2020 18:32:30
User entered '125'	Erika Faust (b) (4) (b) (4)	21 Oct 2020 16:03:37

US3542053
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 08:13:30
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User entered 'mmHg'	System	21 Oct 2020 16:03:37

FDA-CBER-2022-1614-2660724

US3542053
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 08:13:30
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Oct 2020 18:32:30
User entered '75'	Erika Faust (b) (4) (b) (4)	21 Oct 2020 16:03:37

US3542053
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 08:13:30
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User entered 'mmHg'	System	21 Oct 2020 16:03:37

FDA-CBER-2022-1614-2660726

US3542053
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 08:13:30
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21

FDA-CBER-2022-1614-2660727

US3542053
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 08:13:30
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21

FDA-CBER-2022-1614-2660728

US3542053
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Generated On: 10 Jun 2021 08:13:30
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Oct 2020 18:32:30
User entered 'No (N)'	Erika Faust (b) (4) (b) (4)	21 Oct 2020 16:02:46

US3542053
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Generated On: 10 Jun 2021 08:13:30
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Oct 2020 18:32:30
User entered empty.	Erika Faust (b) (4) (b) (4)	21 Oct 2020 16:02:46

US3542053
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 08:13:30
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Oct 2020 18:32:30
User entered 'Yes (Y)'	Erika Faust (b) (4) (b) (4)	21 Oct 2020 16:02:38

US3542053
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 08:13:30
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Oct 2020 18:32:30
User entered '21 Oct 2020' reason for change: Data Entry Error	Erika Faust (b) (4) (b) (4)	21 Oct 2020 16:03:45
User entered '20 Oct 2020'	Erika Faust (b) (4) (b) (4)	21 Oct 2020 16:02:38

US3542053
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 08:13:30
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Oct 2020 18:32:30
User entered '09:01'	Erika Faust (b) (4) (b) (4)	21 Oct 2020 16:02:38

US3542053
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 08:13:30
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User entered '21 Oct 2020 09:01'	System	21 Oct 2020 16:03:45
User entered '20 Oct 2020 09:01'	System	21 Oct 2020 16:02:38

US3542053
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 10 Jun 2021 08:13:30
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Oct 2020 18:32:30
User entered 'Yes (Y)'	Erika Faust (b) (4) (b) (4)	21 Oct 2020 16:02:19

US3542053
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 10 Jun 2021 08:13:30
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User entered '1'	System	21 Oct 2020 16:02:19

FDA-CBER-2022-1614-2660736

US3542053
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:54:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:15:36
Data entry locked.	System	25 Aug 2020 15:29:29
User entered 'Day 64'	System	25 Aug 2020 15:29:29

US3542053
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:54:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:15:36

FDA-CBER-2022-1614-2660738

US3542053
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:54:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:15:36

FDA-CBER-2022-1614-2660739

US3542053
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:54:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:15:36

FDA-CBER-2022-1614-2660740

US3542053
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:54:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:15:36

FDA-CBER-2022-1614-2660741

US3542053
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:54:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:15:36

FDA-CBER-2022-1614-2660742

US3542053
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:54:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:15:36

FDA-CBER-2022-1614-2660743

US3542053
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:54:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:15:36

FDA-CBER-2022-1614-2660744

US3542053
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:54:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:15:36

US3542053
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:54:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:15:36

FDA-CBER-2022-1614-2660746

US3542053
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:54:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:15:36

FDA-CBER-2022-1614-2660747

US3542053
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:54:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:15:36

FDA-CBER-2022-1614-2660748

US3542053
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:54:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:15:36

FDA-CBER-2022-1614-2660749

US3542053
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:54:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:15:36

FDA-CBER-2022-1614-2660750

US3542053
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:54:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:15:36

US3542053
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:54:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:15:36

US3542053
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:54:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:15:36

FDA-CBER-2022-1614-2660753

US3542053
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:54:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:15:36

US3542053
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:54:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:15:36

FDA-CBER-2022-1614-2660755

US3542053
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:54:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:15:36

FDA-CBER-2022-1614-2660756

US3542053
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:54:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:15:36

FDA-CBER-2022-1614-2660757

US3542053
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:54:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:15:36

FDA-CBER-2022-1614-2660758

US3542053
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:54:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:15:36

FDA-CBER-2022-1614-2660759

US3542053
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:54:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:15:36

FDA-CBER-2022-1614-2660760

US3542053
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:54:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:15:36

FDA-CBER-2022-1614-2660761

US3542053
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:54:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:15:36

FDA-CBER-2022-1614-2660762

US3542053
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:54:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:15:36
Data entry locked.	System	25 Aug 2020 15:29:29
User entered '25 Oct 2020 00:01'	System	25 Aug 2020 15:29:29

US3542053
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:54:05
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:15:36
Data entry locked.	System	25 Aug 2020 15:29:29
User entered '29 Oct 2020 23:59'	System	25 Aug 2020 15:29:29

US3542053
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
Data entry locked.	System	25 Aug 2020 15:29:29
User entered 'Day 71'	System	25 Aug 2020 15:29:29

FDA-CBER-2022-1614-2660765

US3542053
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-11-05T11:53:57', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'b7500fd3-0646-469a-81bc-23ac3cb441af'	System	05 Nov 2020 16:54:25
User entered 'No (N)'	System	05 Nov 2020 16:54:25

FDA-CBER-2022-1614-2660766

US3542053

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-11-05T11:54:05', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'b7500fd3-0646-469a-81bc-23ac3cb441af'	System	05 Nov 2020 16:54:25
User entered 'No (N)'	System	05 Nov 2020 16:54:25

US3542053
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-11-05T11:54:23', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'b7500fd3-0646-469a-81bc-23ac3cb441af'	System	05 Nov 2020 16:54:25
User entered '05 Nov 2020 11:54:23'	System	05 Nov 2020 16:54:25

FDA-CBER-2022-1614-2660768

US3542053
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
Data entry locked.	System	25 Aug 2020 15:29:29
User entered '01 Nov 2020 00:01'	System	25 Aug 2020 15:29:29

US3542053
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
Data entry locked.	System	25 Aug 2020 15:29:29
User entered '05 Nov 2020 23:59'	System	25 Aug 2020 15:29:29

FDA-CBER-2022-1614-2660770

US3542053
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
Data entry locked.	System	25 Aug 2020 15:29:29
User entered 'Day 78'	System	25 Aug 2020 15:29:29

FDA-CBER-2022-1614-2660771

US3542053
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-11-12T12:13:57', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '8be22347-b791-4864-af5f-552b6258a4c8'	System	12 Nov 2020 17:14:15
User entered 'No (N)'	System	12 Nov 2020 17:14:15

FDA-CBER-2022-1614-2660772

US3542053

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-11-12T12:14:03', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '8be22347-b791-4864-af5f-552b6258a4c8'	System	12 Nov 2020 17:14:15
User entered 'No (N)'	System	12 Nov 2020 17:14:15

US3542053
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-11-12T12:14:08', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '8be22347-b791-4864-af5f-552b6258a4c8'	System	12 Nov 2020 17:14:15
User entered '12 Nov 2020 12:14:08'	System	12 Nov 2020 17:14:15

FDA-CBER-2022-1614-2660774

US3542053
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
Data entry locked.	System	25 Aug 2020 15:29:29
User entered '08 Nov 2020 00:01'	System	25 Aug 2020 15:29:29

US3542053
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 14:37:49
Data entry locked.	System	25 Aug 2020 15:29:29
User entered '12 Nov 2020 23:59'	System	25 Aug 2020 15:29:29

FDA-CBER-2022-1614-2660776

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 02:15:36

US3542053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-11-21T00:34:40', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'cc344bf7-e68d-4ab2-a7ea-a3d6274b6c02'	System	21 Nov 2020 05:37:09
User entered 'No (N)'	System	21 Nov 2020 05:37:09

US3542053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-11-21T00:34:45', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'cc344bf7-e68d-4ab2-a7ea-a3d6274b6c02'	System	21 Nov 2020 05:37:09
User entered 'No (N)'	System	21 Nov 2020 05:37:09

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-11-21T00:34:49', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'cc344bf7-e68d-4ab2-a7ea-a3d6274b6c02'	System	21 Nov 2020 05:37:09
User entered '21 Nov 2020 00:34:49'	System	21 Nov 2020 05:37:09

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '19 Nov 2020 00:01'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '23 Nov 2020 23:59'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 02:15:36

US3542053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-11-26T00:02:06', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '140561e8-0998-4a8a-8843-a1bfd0dc1fd1'	System	26 Nov 2020 05:02:30
User entered 'No (N)'	System	26 Nov 2020 05:02:30

US3542053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-11-26T00:02:13', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '140561e8-0998-4a8a-8843-a1bfd0dc1fd1'	System	26 Nov 2020 05:02:30
User entered 'No (N)'	System	26 Nov 2020 05:02:30

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-11-26T00:02:22', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '140561e8-0998-4a8a-8843-a1bfd0dc1fd1'	System	26 Nov 2020 05:02:30
User entered '26 Nov 2020 00:02:22'	System	26 Nov 2020 05:02:30

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '26 Nov 2020 00:01'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '30 Nov 2020 23:59'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 02:15:36

US3542053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-12-03T00:01:40', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'e9ad2664-8d0f-46eb-a87c-d7de7f44df40'	System	03 Dec 2020 05:02:15
User entered 'No (N)'	System	03 Dec 2020 05:02:15

US3542053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-12-03T00:01:51', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'e9ad2664-8d0f-46eb-a87c-d7de7f44df40'	System	03 Dec 2020 05:02:15
User entered 'No (N)'	System	03 Dec 2020 05:02:15

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-12-03T00:02:00', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'e9ad2664-8d0f-46eb-a87c-d7de7f44df40'	System	03 Dec 2020 05:02:15
User entered '03 Dec 2020 00:02:00'	System	03 Dec 2020 05:02:15

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '03 Dec 2020 00:01'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '07 Dec 2020 23:59'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 02:15:36

US3542053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-12-10T00:09:24', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '3ca82f69-2a23-4c08-9723-b8e50e328d03'	System	10 Dec 2020 05:09:40
User entered 'No (N)'	System	10 Dec 2020 05:09:40

US3542053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-12-10T00:09:28', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '3ca82f69-2a23-4c08-9723-b8e50e328d03'	System	10 Dec 2020 05:09:40
User entered 'No (N)'	System	10 Dec 2020 05:09:40

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-12-10T00:09:32', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '3ca82f69-2a23-4c08-9723-b8e50e328d03'	System	10 Dec 2020 05:09:40
User entered '10 Dec 2020 00:09:32'	System	10 Dec 2020 05:09:40

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '10 Dec 2020 00:01'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '14 Dec 2020 23:59'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 02:15:36

US3542053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:30

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

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 10:19:58
Query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' answered with 'participant had atrial flutter during this timeframe and that is the reason she replied "YES"' (Site from DM).	Elissa Malkin (b) (4) (b) (4)	08 Mar 2021 20:54:56
User opened query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	06 Mar 2021 13:22:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-12-17T00:19:04', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'e417c23b-4605-4053-a0a9-0f10cddebd38'	System	17 Dec 2020 05:20:03
User entered 'Yes (Y)'	System	17 Dec 2020 05:20:03

US3542053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-12-17T00:19:09', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'e417c23b-4605-4053-a0a9-0f10cddebd38'	System	17 Dec 2020 05:20:03
User entered 'No (N)'	System	17 Dec 2020 05:20:03

US3542053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-12-17T00:19:19', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'e417c23b-4605-4053-a0a9-0f10cddebd38'	System	17 Dec 2020 05:20:03
User entered 'No (N)'	System	17 Dec 2020 05:20:03

US3542053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-12-17T00:19:27', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'e417c23b-4605-4053-a0a9-0f10cddebd38'	System	17 Dec 2020 05:20:03
User entered 'Yes (Y)'	System	17 Dec 2020 05:20:03

US3542053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-12-17T00:19:42', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'e417c23b-4605-4053-a0a9-0f10cddebd38'	System	17 Dec 2020 05:20:03
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	17 Dec 2020 05:20:03

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2020-12-17T00:19:52', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'e417c23b-4605-4053-a0a9-0f10cddebd38'	System	17 Dec 2020 05:20:03
User entered '17 Dec 2020 00:19:52'	System	17 Dec 2020 05:20:03

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '17 Dec 2020 00:01'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '21 Dec 2020 23:59'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '24 Dec 2020 00:01'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '28 Dec 2020 23:59'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 02:15:36

US3542053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2021-01-04T11:59:48', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '31909db0-2157-4d6f-98e1-9eca4f468f60'	System	04 Jan 2021 17:00:05
User entered 'No (N)'	System	04 Jan 2021 17:00:05

US3542053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2021-01-04T11:59:53', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '31909db0-2157-4d6f-98e1-9eca4f468f60'	System	04 Jan 2021 17:00:05
User entered 'No (N)'	System	04 Jan 2021 17:00:05

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2021-01-04T12:00:00', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '31909db0-2157-4d6f-98e1-9eca4f468f60'	System	04 Jan 2021 17:00:05
User entered '04 Jan 2021 12:00:00'	System	04 Jan 2021 17:00:05

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '31 Dec 2020 00:01'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '04 Jan 2021 23:59'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 02:15:36

US3542053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2021-01-10T18:07:11', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '0043c711-832b-4242-946d-ac75dfd6e868'	System	10 Jan 2021 23:07:23
User entered 'No (N)'	System	10 Jan 2021 23:07:23

US3542053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2021-01-10T18:07:14', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '0043c711-832b-4242-946d-ac75dfd6e868'	System	10 Jan 2021 23:07:23
User entered 'No (N)'	System	10 Jan 2021 23:07:23

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2021-01-10T18:07:20', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '0043c711-832b-4242-946d-ac75dfd6e868'	System	10 Jan 2021 23:07:23
User entered '10 Jan 2021 18:07:20'	System	10 Jan 2021 23:07:23

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '07 Jan 2021 00:01'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '11 Jan 2021 23:59'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 02:15:36

US3542053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2021-01-14T00:01:44', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '3e6ddbe7-f369-4a3a-86ae-894837cf57fe'	System	14 Jan 2021 05:02:17
User entered 'No (N)'	System	14 Jan 2021 05:02:17

US3542053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2021-01-14T00:01:47', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '3e6ddbe7-f369-4a3a-86ae-894837cf57fe'	System	14 Jan 2021 05:02:17
User entered 'No (N)'	System	14 Jan 2021 05:02:17

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2021-01-14T00:01:51', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '3e6ddbe7-f369-4a3a-86ae-894837cf57fe'	System	14 Jan 2021 05:02:17
User entered '14 Jan 2021 00:01:51'	System	14 Jan 2021 05:02:17

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '14 Jan 2021 00:01'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '18 Jan 2021 23:59'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '21 Jan 2021 00:01'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '25 Jan 2021 23:59'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 02:15:36

US3542053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2021-01-28T00:23:09', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '4e2a6baa-41df-4e26-ab72-e6a8c95afad9'	System	28 Jan 2021 05:23:29
User entered 'No (N)'	System	28 Jan 2021 05:23:29

US3542053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2021-01-28T00:23:15', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '4e2a6baa-41df-4e26-ab72-e6a8c95afad9'	System	28 Jan 2021 05:23:29
User entered 'No (N)'	System	28 Jan 2021 05:23:29

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2021-01-28T00:23:28', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '4e2a6baa-41df-4e26-ab72-e6a8c95afad9'	System	28 Jan 2021 05:23:29
User entered '28 Jan 2021 00:23:28'	System	28 Jan 2021 05:23:29

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '28 Jan 2021 00:01'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '01 Feb 2021 23:59'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 02:15:36

US3542053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2021-02-04T00:01:26', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '46d37996-e693-4558-aae6-9637496c32c5'	System	04 Feb 2021 05:02:09
User entered 'No (N)'	System	04 Feb 2021 05:02:09

US3542053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2021-02-04T00:01:35', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '46d37996-e693-4558-aae6-9637496c32c5'	System	04 Feb 2021 05:02:09
User entered 'No (N)'	System	04 Feb 2021 05:02:09

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2021-02-04T00:01:41', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '46d37996-e693-4558-aae6-9637496c32c5'	System	04 Feb 2021 05:02:09
User entered '04 Feb 2021 00:01:41'	System	04 Feb 2021 05:02:09

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '04 Feb 2021 00:01'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '08 Feb 2021 23:59'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '11 Feb 2021 00:01'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '15 Feb 2021 23:59'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 02:15:36

US3542053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2021-02-22T12:16:37', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '982a16b8-026f-4332-9fad-f0d55bfe9892'	System	22 Feb 2021 17:18:54
User entered 'No (N)'	System	22 Feb 2021 17:18:54

US3542053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2021-02-22T12:16:42', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '982a16b8-026f-4332-9fad-f0d55bfe9892'	System	22 Feb 2021 17:18:54
User entered 'No (N)'	System	22 Feb 2021 17:18:54

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2021-02-22T12:16:48', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '982a16b8-026f-4332-9fad-f0d55bfe9892'	System	22 Feb 2021 17:18:54
User entered '22 Feb 2021 12:16:48'	System	22 Feb 2021 17:18:54

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '18 Feb 2021 00:01'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '22 Feb 2021 23:59'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 02:15:36

US3542053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2021-02-25T00:05:09', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '95b60f8a-4225-4cf3-aeb7-3ee8bc92afb0'	System	25 Feb 2021 05:06:16
User entered 'No (N)'	System	25 Feb 2021 05:06:16

US3542053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2021-02-25T00:05:14', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '95b60f8a-4225-4cf3-aeb7-3ee8bc92afb0'	System	25 Feb 2021 05:06:16
User entered 'No (N)'	System	25 Feb 2021 05:06:16

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2021-02-25T00:05:18', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '95b60f8a-4225-4cf3-aeb7-3ee8bc92afb0'	System	25 Feb 2021 05:06:16
User entered '25 Feb 2021 00:05:18'	System	25 Feb 2021 05:06:16

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '25 Feb 2021 00:01'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '01 Mar 2021 23:59'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 02:15:36

US3542053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2021-03-08T12:17:54', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '3bd3c45a-05ad-4395-9429-1125a063cd16'	System	08 Mar 2021 17:24:12
User entered 'No (N)'	System	08 Mar 2021 17:24:12

US3542053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2021-03-08T12:17:56', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '3bd3c45a-05ad-4395-9429-1125a063cd16'	System	08 Mar 2021 17:24:12
User entered 'No (N)'	System	08 Mar 2021 17:24:12

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2021-03-08T12:18:00', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '3bd3c45a-05ad-4395-9429-1125a063cd16'	System	08 Mar 2021 17:24:12
User entered '08 Mar 2021 12:18:00'	System	08 Mar 2021 17:24:12

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '04 Mar 2021 00:01'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '08 Mar 2021 23:59'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 02:15:36

US3542053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2021-03-11T00:13:56', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'dac16cdc-1789-4d2d-9127-9ca4b57346c3'	System	11 Mar 2021 05:14:10
User entered 'No (N)'	System	11 Mar 2021 05:14:10

US3542053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2021-03-11T00:14:00', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'dac16cdc-1789-4d2d-9127-9ca4b57346c3'	System	11 Mar 2021 05:14:10
User entered 'No (N)'	System	11 Mar 2021 05:14:10

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2021-03-11T00:14:04', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'dac16cdc-1789-4d2d-9127-9ca4b57346c3'	System	11 Mar 2021 05:14:10
User entered '11 Mar 2021 00:14:04'	System	11 Mar 2021 05:14:10

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '11 Mar 2021 00:01'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '15 Mar 2021 23:59'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 02:15:36

US3542053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2021-03-21T18:01:06-04:00', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'fa2e1f46-17f9-4628-8404-182246f26905'	System	21 Mar 2021 22:04:13
User entered 'No (N)'	System	21 Mar 2021 22:04:13

US3542053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2021-03-21T18:01:11-04:00', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'fa2e1f46-17f9-4628-8404-182246f26905'	System	21 Mar 2021 22:04:13
User entered 'No (N)'	System	21 Mar 2021 22:04:13

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2021-03-21T18:01:14-04:00', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'fa2e1f46-17f9-4628-8404-182246f26905'	System	21 Mar 2021 22:04:13
User entered '21 Mar 2021 18:01:14'	System	21 Mar 2021 22:04:13

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '18 Mar 2021 00:01'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '22 Mar 2021 23:59'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 02:15:36

US3542053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2021-03-25T00:05:34-04:00', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'ea8cb1de-c8ad-41f1-9e05-34aa09424c30'	System	25 Mar 2021 04:05:44
User entered 'No (N)'	System	25 Mar 2021 04:05:44

US3542053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2021-03-25T00:05:38-04:00', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'ea8cb1de-c8ad-41f1-9e05-34aa09424c30'	System	25 Mar 2021 04:05:44
User entered 'No (N)'	System	25 Mar 2021 04:05:44

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2021-03-25T00:05:41-04:00', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: 'ea8cb1de-c8ad-41f1-9e05-34aa09424c30'	System	25 Mar 2021 04:05:44
User entered '25 Mar 2021 00:05:41'	System	25 Mar 2021 04:05:44

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '25 Mar 2021 00:01'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '29 Mar 2021 23:59'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 02:15:36

US3542053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2021-04-01T00:08:25-04:00', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '373a69cc-2dcd-4fd5-b4b0-3a0550dc08e1'	System	01 Apr 2021 04:08:38
User entered 'No (N)'	System	01 Apr 2021 04:08:38

US3542053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2021-04-01T00:08:28-04:00', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '373a69cc-2dcd-4fd5-b4b0-3a0550dc08e1'	System	01 Apr 2021 04:08:38
User entered 'No (N)'	System	01 Apr 2021 04:08:38

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2021-04-01T00:08:35-04:00', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '373a69cc-2dcd-4fd5-b4b0-3a0550dc08e1'	System	01 Apr 2021 04:08:38
User entered '01 Apr 2021 00:08:35'	System	01 Apr 2021 04:08:38

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '01 Apr 2021 00:01'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '05 Apr 2021 23:59'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 02:15:36

US3542053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2021-04-10T21:04:06-04:00', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '54229f2c-8847-41b3-8151-91fed82c7856'	System	11 Apr 2021 01:12:21
User entered 'No (N)'	System	11 Apr 2021 01:12:21

US3542053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2021-04-10T21:04:11-04:00', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '54229f2c-8847-41b3-8151-91fed82c7856'	System	11 Apr 2021 01:12:21
User entered 'No (N)'	System	11 Apr 2021 01:12:21

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2021-04-10T21:04:15-04:00', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '54229f2c-8847-41b3-8151-91fed82c7856'	System	11 Apr 2021 01:12:21
User entered '10 Apr 2021 21:04:15'	System	11 Apr 2021 01:12:21

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '08 Apr 2021 00:01'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '12 Apr 2021 23:59'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 02:15:36

US3542053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2021-04-15T07:02:42-04:00', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '1818a5d6-37d6-4e36-90ad-080748235594'	System	15 Apr 2021 11:03:01
User entered 'No (N)'	System	15 Apr 2021 11:03:01

US3542053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2021-04-15T07:02:49-04:00', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '1818a5d6-37d6-4e36-90ad-080748235594'	System	15 Apr 2021 11:03:01
User entered 'No (N)'	System	15 Apr 2021 11:03:01

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2021-04-15T07:02:59-04:00', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '1818a5d6-37d6-4e36-90ad-080748235594'	System	15 Apr 2021 11:03:01
User entered '15 Apr 2021 07:02:59'	System	15 Apr 2021 11:03:01

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '15 Apr 2021 00:01'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '19 Apr 2021 23:59'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '22 Apr 2021 00:01'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '26 Apr 2021 23:59'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 02:15:36

US3542053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2021-05-03T13:19:15-04:00', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '3344b304-27ca-4fb5-bb7c-fe0646497771'	System	03 May 2021 17:20:37
User entered 'No (N)'	System	03 May 2021 17:20:37

US3542053

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:13:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2021-05-03T13:19:17-04:00', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '3344b304-27ca-4fb5-bb7c-fe0646497771'	System	03 May 2021 17:20:37
User entered 'No (N)'	System	03 May 2021 17:20:37

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2021-05-03T13:19:22-04:00', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '3344b304-27ca-4fb5-bb7c-fe0646497771'	System	03 May 2021 17:20:37
User entered '03 May 2021 13:19:22'	System	03 May 2021 17:20:37

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '29 Apr 2021 00:01'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '03 May 2021 23:59'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '06 May 2021 00:01'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '10 May 2021 23:59'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '13 May 2021 00:01'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '17 May 2021 23:59'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '20 May 2021 00:01'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '24 May 2021 23:59'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '27 May 2021 00:01'	System	20 Nov 2020 02:15:36

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US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '31 May 2021 23:59'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '03 Jun 2021 00:01'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '07 Jun 2021 23:59'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '10 Jun 2021 00:01'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '14 Jun 2021 23:59'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '17 Jun 2021 00:01'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '21 Jun 2021 23:59'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '24 Jun 2021 00:01'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '28 Jun 2021 23:59'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '01 Jul 2021 00:01'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '05 Jul 2021 23:59'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '08 Jul 2021 00:01'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '12 Jul 2021 23:59'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '15 Jul 2021 00:01'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '19 Jul 2021 23:59'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '22 Jul 2021 00:01'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '26 Jul 2021 23:59'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '29 Jul 2021 00:01'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '02 Aug 2021 23:59'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '05 Aug 2021 00:01'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '09 Aug 2021 23:59'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '12 Aug 2021 00:01'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '16 Aug 2021 23:59'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '19 Aug 2021 00:01'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '23 Aug 2021 23:59'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '26 Aug 2021 00:01'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '30 Aug 2021 23:59'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '02 Sep 2021 00:01'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '06 Sep 2021 23:59'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '09 Sep 2021 00:01'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '13 Sep 2021 23:59'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '16 Sep 2021 00:01'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '20 Sep 2021 23:59'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '23 Sep 2021 00:01'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '27 Sep 2021 23:59'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '30 Sep 2021 00:01'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '04 Oct 2021 23:59'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '07 Oct 2021 00:01'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '11 Oct 2021 23:59'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '14 Oct 2021 00:01'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '18 Oct 2021 23:59'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '21 Oct 2021 00:01'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '25 Oct 2021 23:59'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '28 Oct 2021 00:01'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '01 Nov 2021 23:59'	System	20 Nov 2020 02:15:36

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US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '04 Nov 2021 00:01'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '08 Nov 2021 23:59'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '11 Nov 2021 00:01'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '15 Nov 2021 23:59'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '18 Nov 2021 00:01'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '22 Nov 2021 23:59'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '25 Nov 2021 00:01'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '29 Nov 2021 23:59'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '02 Dec 2021 00:01'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '06 Dec 2021 23:59'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '09 Dec 2021 00:01'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '13 Dec 2021 23:59'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '16 Dec 2021 00:01'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '20 Dec 2021 23:59'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '23 Dec 2021 00:01'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '27 Dec 2021 23:59'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '30 Dec 2021 00:01'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '03 Jan 2022 23:59'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '06 Jan 2022 00:01'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '10 Jan 2022 23:59'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '13 Jan 2022 00:01'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '17 Jan 2022 23:59'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '20 Jan 2022 00:01'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '24 Jan 2022 23:59'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '27 Jan 2022 00:01'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '31 Jan 2022 23:59'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '03 Feb 2022 00:01'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '07 Feb 2022 23:59'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '10 Feb 2022 00:01'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '14 Feb 2022 23:59'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '17 Feb 2022 00:01'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '21 Feb 2022 23:59'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '24 Feb 2022 00:01'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '28 Feb 2022 23:59'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '03 Mar 2022 00:01'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '07 Mar 2022 23:59'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '10 Mar 2022 00:01'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '14 Mar 2022 23:59'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '17 Mar 2022 00:01'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '21 Mar 2022 23:59'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '24 Mar 2022 00:01'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '28 Mar 2022 23:59'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '31 Mar 2022 00:01'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '04 Apr 2022 23:59'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '07 Apr 2022 00:01'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '11 Apr 2022 23:59'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '14 Apr 2022 00:01'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '18 Apr 2022 23:59'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '21 Apr 2022 00:01'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '25 Apr 2022 23:59'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '28 Apr 2022 00:01'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '02 May 2022 23:59'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '05 May 2022 00:01'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '09 May 2022 23:59'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '12 May 2022 00:01'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '16 May 2022 23:59'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '19 May 2022 00:01'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '23 May 2022 23:59'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '26 May 2022 00:01'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '30 May 2022 23:59'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '02 Jun 2022 00:01'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '06 Jun 2022 23:59'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '09 Jun 2022 00:01'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '13 Jun 2022 23:59'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '16 Jun 2022 00:01'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '20 Jun 2022 23:59'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '23 Jun 2022 00:01'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '27 Jun 2022 23:59'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '30 Jun 2022 00:01'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '04 Jul 2022 23:59'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '07 Jul 2022 00:01'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '11 Jul 2022 23:59'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '14 Jul 2022 00:01'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '18 Jul 2022 23:59'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '21 Jul 2022 00:01'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '25 Jul 2022 23:59'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '28 Jul 2022 00:01'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '01 Aug 2022 23:59'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '04 Aug 2022 00:01'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '08 Aug 2022 23:59'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '11 Aug 2022 00:01'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '15 Aug 2022 23:59'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '18 Aug 2022 00:01'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '22 Aug 2022 23:59'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '25 Aug 2022 00:01'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '29 Aug 2022 23:59'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '01 Sep 2022 00:01'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '05 Sep 2022 23:59'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '08 Sep 2022 00:01'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '12 Sep 2022 23:59'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '15 Sep 2022 00:01'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '19 Sep 2022 23:59'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '22 Sep 2022 00:01'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '26 Sep 2022 23:59'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '29 Sep 2022 00:01'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '03 Oct 2022 23:59'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '06 Oct 2022 00:01'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '10 Oct 2022 23:59'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '13 Oct 2022 00:01'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '17 Oct 2022 23:59'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '20 Oct 2022 00:01'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '24 Oct 2022 23:59'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '27 Oct 2022 00:01'	System	20 Nov 2020 02:15:36

US3542053
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:13:30
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:15:36
Amendment Manager: User entered '31 Oct 2022 23:59'	System	20 Nov 2020 02:15:36

US3542053

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:13:30

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:54:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2021-03-08T12:18:21', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '06a3e533-17ff-4810-8973-534452062a43'	System	08 Mar 2021 17:24:23
User entered 'No (N)'	System	08 Mar 2021 17:24:23

US3542053
Folder: Cosmetic Injections and Dermal Fillers
Form: Cosmetic Injection_ Dermal Filler eDiary (1)
Generated On: 10 Jun 2021 08:13:30
Date & Time of Submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 15:54:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3D6ECC91-4025-4CAB-9371-85D4EFBAF6FA)', Time: '2021-03-08T12:18:24', User OID: 'PatientReportedOutcome (US3542053)', ODM File OID: '06a3e533-17ff-4810-8973-534452062a43'	System	08 Mar 2021 17:24:23
User entered '08 Mar 2021 12:18:24'	System	08 Mar 2021 17:24:23

US3542053
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 10 Jun 2021 08:13:30
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Nov 2020 04:10:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Nov 2020 17:13:16

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US3542053
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 10 Jun 2021 08:13:30
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Nov 2020 04:10:23
User entered '18 Nov 2020'	(b) (4), (b) (6)	19 Nov 2020 17:13:16

US3542053
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 10 Jun 2021 08:13:30
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Nov 2020 04:10:23
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	19 Nov 2020 17:13:16

US3542053
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 10 Jun 2021 08:13:30
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4)	20 Nov 2020 04:10:23
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:13:16

US3542053
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 10 Jun 2021 08:13:30
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Nov 2020 04:10:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Nov 2020 17:13:21

US3542053
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 10 Jun 2021 08:13:30
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 06:50:21
User entered '1'	System	19 Nov 2020 17:13:21

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US3542053
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 10 Jun 2021 08:13:30
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:52:49
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Dec 2020 22:58:26
User entered 'Yes (Y)'	Erika Faust (b) (4) (b) (4)	18 Dec 2020 16:57:29

US3542053
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 10 Jun 2021 08:13:30
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:52:49
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Dec 2020 22:58:26
User entered '17 Dec 2020'	Erika Faust (b) (4) (b) (4)	18 Dec 2020 16:57:29

FDA-CBER-2022-1614-2661155

US3542053
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 10 Jun 2021 08:13:30
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:52:49
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Dec 2020 22:58:26
User entered 'Contact Made (CONTACT MADE)'	Erika Faust (b) (4) (b) (4)	18 Dec 2020 16:57:29

US3542053
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 10 Jun 2021 08:13:30
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:52:49
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Dec 2020 22:58:26
User entered empty.	Erika Faust (b) (4) (b) (4)	18 Dec 2020 16:57:29

US3542053
Folder: Safety Call Day 119 (1)
Form: Continuing
Generated On: 10 Jun 2021 08:13:30
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:52:49
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Dec 2020 22:58:26
User entered 'Yes (Y)'	Erika Faust (b) (4) (b) (4)	18 Dec 2020 16:57:21

US3542053
Folder: Safety Call Day 119 (1)
Form: Continuing
Generated On: 10 Jun 2021 08:13:30
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:52:49
User entered '1'	System	18 Dec 2020 16:57:21

FDA-CBER-2022-1614-2661159

US3542053
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 10 Jun 2021 08:13:30
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:52:49
User signature succeeded.	David Diemert (b) (4) (b) (4)	22 Jan 2021 18:10:54
User entered 'Yes (Y)'	Taylor Ladson (b) (4) (b) (4)	22 Jan 2021 17:57:55

US3542053
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 10 Jun 2021 08:13:30
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:52:49
User signature succeeded.	David Diemert (b) (4) (b) (4)	22 Jan 2021 18:10:54
User entered '16 Jan 2021'	Taylor Ladson (b) (4) (b) (4)	22 Jan 2021 17:57:55

US3542053
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 10 Jun 2021 08:13:30
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:52:49
User signature succeeded.	David Diemert (b) (4) (b) (4)	22 Jan 2021 18:10:54
User entered 'Contact Made (CONTACT MADE)'	Taylor Ladson (b) (4) (b) (4)	22 Jan 2021 17:57:55

US3542053
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 10 Jun 2021 08:13:30
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:52:49
User signature succeeded.	David Diemert (b) (4) (b) (4)	22 Jan 2021 18:10:54
User entered empty.	Taylor Ladson (b) (4) (b) (4)	22 Jan 2021 17:57:55

US3542053
Folder: Safety Call Day 149 (1)
Form: Continuing
Generated On: 10 Jun 2021 08:13:30
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:52:49
User signature succeeded.	David Diemert (b) (4) (b) (4)	22 Jan 2021 18:10:54
User entered 'Yes (Y)'	Taylor Ladson (b) (4) (b) (4)	22 Jan 2021 17:58:00

US3542053
Folder: Safety Call Day 149 (1)
Form: Continuing
Generated On: 10 Jun 2021 08:13:30
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:52:49
User entered '1'	System	22 Jan 2021 17:58:00

US3542053
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 10 Jun 2021 08:13:30
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:52:49
User signature succeeded.	David Diemert (b) (4) (b) (4)	23 Feb 2021 16:40:27
User entered 'Yes (Y)'	Erika Faust (b) (4) (b) (4)	19 Feb 2021 17:09:24

US3542053
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 10 Jun 2021 08:13:30
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:52:49
User signature succeeded.	David Diemert (b) (4) (b) (4)	23 Feb 2021 16:40:27
User entered '17 Feb 2021'	Erika Faust (b) (4) (b) (4)	19 Feb 2021 17:09:24

US3542053
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 10 Jun 2021 08:13:30
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:52:49
User signature succeeded.	David Diemert (b) (4) (b) (4)	23 Feb 2021 16:40:27
User entered 'Contact Made (CONTACT MADE)'	Erika Faust (b) (4) (b) (4)	19 Feb 2021 17:09:24

US3542053
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 10 Jun 2021 08:13:30
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:52:49
User signature succeeded.	David Diemert (b) (4) (b) (4)	23 Feb 2021 16:40:27
User entered empty.	Erika Faust (b) (4) (b) (4)	19 Feb 2021 17:09:24

US3542053
Folder: Safety Call Day 179 (1)
Form: Continuing
Generated On: 10 Jun 2021 08:13:30
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:52:49
User signature succeeded.	David Diemert (b) (4) (b) (4)	23 Feb 2021 16:40:27
User entered 'Yes (Y)'	Erika Faust (b) (4) (b) (4)	19 Feb 2021 17:09:29

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US3542053
Folder: Safety Call Day 179 (1)
Form: Continuing
Generated On: 10 Jun 2021 08:13:30
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:52:49
User entered '1'	System	19 Feb 2021 17:09:29

FDA-CBER-2022-1614-2661171

US3542053
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 10 Jun 2021 08:13:30
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:52:49
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 17:35:26
User signature succeeded.	David Diemert (b) (4) (b) (4)	26 Mar 2021 16:51:28
User entered 'Yes (Y)'	Erika Faust (b) (4) (b) (4)	25 Mar 2021 18:02:07

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US3542053
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 10 Jun 2021 08:13:30
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:52:49
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 17:35:26
User signature succeeded.	David Diemert (b) (4) (b) (4)	26 Mar 2021 16:51:28
User entered '24 Mar 2021'	Erika Faust (b) (4) (b) (4)	25 Mar 2021 18:02:07

FDA-CBER-2022-1614-2661173

US3542053
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 10 Jun 2021 08:13:30
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:52:49
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 17:35:26
User signature succeeded.	David Diemert (b) (4) (b) (4)	26 Mar 2021 16:51:28
User entered 'Clinic (Clinic)'	Erika Faust (b) (4) (b) (4)	25 Mar 2021 18:02:07

US3542053
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 10 Jun 2021 08:13:30
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:52:49
User entered 'VISIT4'	System	25 Mar 2021 18:02:07

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US3542053
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 08:13:30
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:52:49
User signature succeeded.	David Diemert (b) (4) (b) (4)	31 Mar 2021 21:13:49
User entered 'No (N)'	Hannah Yellin (b) (4) (b) (4)	31 Mar 2021 17:37:38

FDA-CBER-2022-1614-2661176

US3542053
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 08:13:30
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:52:49
User signature succeeded.	David Diemert (b) (4) (b) (4)	31 Mar 2021 21:13:49
User entered empty.	Hannah Yellin (b) (4) (b) (4)	31 Mar 2021 17:37:38

FDA-CBER-2022-1614-2661177

US3542053
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 08:13:30
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:52:49
User signature succeeded.	David Diemert (b) (4) (b) (4)	31 Mar 2021 21:13:49
User entered empty.	Hannah Yellin (b) (4) (b) (4)	31 Mar 2021 17:37:38

FDA-CBER-2022-1614-2661178

US3542053
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 08:13:30
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:52:49
User entered empty.	System	31 Mar 2021 17:37:38

US3542053
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 08:13:30
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:52:49
User signature succeeded.	David Diemert (b) (4) (b) (4)	31 Mar 2021 21:13:49
User entered empty.	Hannah Yellin (b) (4) (b) (4)	31 Mar 2021 17:37:38

FDA-CBER-2022-1614-2661180

US3542053
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 08:13:30
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:52:49
User signature succeeded.	David Diemert (b) (4) (b) (4)	31 Mar 2021 21:13:49
User entered empty.	Hannah Yellin (b) (4) (b) (4)	31 Mar 2021 17:37:38

US3542053
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 08:13:30
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:52:49
User signature succeeded.	David Diemert (b) (4) (b) (4)	31 Mar 2021 21:13:49
User entered empty.	Hannah Yellin (b) (4) (b) (4)	31 Mar 2021 17:37:38

US3542053
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 08:13:30
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:52:49
User signature succeeded.	David Diemert (b) (4) (b) (4)	31 Mar 2021 21:13:49
User entered empty.	Hannah Yellin (b) (4) (b) (4)	31 Mar 2021 17:37:38

US3542053
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 08:13:30
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:52:49
User entered empty.	System	31 Mar 2021 17:37:38

US3542053
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 08:13:30
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:52:49
User signature succeeded.	David Diemert (b) (4) (b) (4)	31 Mar 2021 21:13:49
User entered empty.	Hannah Yellin (b) (4) (b) (4)	31 Mar 2021 17:37:38

US3542053
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 08:13:30
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:52:49
User entered empty.	System	31 Mar 2021 17:37:38

FDA-CBER-2022-1614-2661186

US3542053
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 08:13:30
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:52:49
User signature succeeded.	David Diemert (b) (4) (b) (4)	31 Mar 2021 21:13:49
User entered empty.	Hannah Yellin (b) (4) (b) (4)	31 Mar 2021 17:37:38

US3542053
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 08:13:30
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:52:49
User entered empty.	System	31 Mar 2021 17:37:38

FDA-CBER-2022-1614-2661188

US3542053
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 08:13:30
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:52:49
User signature succeeded.	David Diemert (b) (4) (b) (4)	31 Mar 2021 21:13:49
User entered empty.	Hannah Yellin (b) (4) (b) (4)	31 Mar 2021 17:37:38

FDA-CBER-2022-1614-2661189

US3542053
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 08:13:30
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:52:49
User entered empty.	System	31 Mar 2021 17:37:38

FDA-CBER-2022-1614-2661190

US3542053
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 08:13:30
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:52:49

FDA-CBER-2022-1614-2661191

US3542053
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 08:13:30
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:52:49

FDA-CBER-2022-1614-2661192

US3542053
Folder: Visit 4 Day 209 (1)
Form: Physical Examination
Generated On: 10 Jun 2021 08:13:30
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:52:49
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 17:35:33
User signature succeeded.	David Diemert (b) (4) (b) (4)	26 Mar 2021 16:51:28
User entered 'No (N)'	Erika Faust (b) (4) (b) (4)	25 Mar 2021 18:02:14

FDA-CBER-2022-1614-2661193

US3542053
Folder: Visit 4 Day 209 (1)
Form: Physical Examination
Generated On: 10 Jun 2021 08:13:30
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:52:49
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 17:35:33
User signature succeeded.	David Diemert (b) (4) (b) (4)	26 Mar 2021 16:51:28
User entered empty.	Erika Faust (b) (4) (b) (4)	25 Mar 2021 18:02:14

US3542053
Folder: Visit 4 Day 209 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 08:13:30
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:52:49
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 17:35:38
User signature succeeded.	David Diemert (b) (4) (b) (4)	26 Mar 2021 16:51:28
User entered 'Yes (Y)'	Erika Faust (b) (4) (b) (4)	25 Mar 2021 18:02:28

US3542053
Folder: Visit 4 Day 209 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 08:13:30
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:52:49
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 17:35:38
User signature succeeded.	David Diemert (b) (4) (b) (4)	26 Mar 2021 16:51:28
User entered '24 Mar 2021'	Erika Faust (b) (4) (b) (4)	25 Mar 2021 18:02:28

US3542053
Folder: Visit 4 Day 209 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 08:13:30
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:52:49
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 17:35:38
User signature succeeded.	David Diemert (b) (4) (b) (4)	26 Mar 2021 16:51:28
User entered '09:03'	Erika Faust (b) (4) (b) (4)	25 Mar 2021 18:02:28

FDA-CBER-2022-1614-2661197

US3542053
Folder: Visit 4 Day 209 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 08:13:30
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:52:49
User entered '24 Mar 2021 09:03'	System	25 Mar 2021 18:02:28

FDA-CBER-2022-1614-2661198

US3542053
Folder: Visit 4 Day 209 (1)
Form: Continuing
Generated On: 10 Jun 2021 08:13:30
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:52:49
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 17:35:43
User signature succeeded.	David Diemert (b) (4) (b) (4)	26 Mar 2021 16:51:28
User entered 'Yes (Y)'	Erika Faust (b) (4) (b) (4)	25 Mar 2021 18:02:32

US3542053
Folder: Visit 4 Day 209 (1)
Form: Continuing
Generated On: 10 Jun 2021 08:13:30
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:52:49
User entered '1'	System	25 Mar 2021 18:02:32

US3542053
Folder: Safety Call Day 239 (1)
Form: Safety Call
Generated On: 10 Jun 2021 08:13:30
Was Contact Attempted?

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Apr 2021 12:55:28
User entered 'Yes (Y)'	Madhu Balachandran (b) (4)	19 Apr 2021 18:41:07

US3542053
Folder: Safety Call Day 239 (1)
Form: Safety Call
Generated On: 10 Jun 2021 08:13:30
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Apr 2021 12:55:28
User entered '16 Apr 2021'	Madhu Balachandran (b) (4)	19 Apr 2021 18:41:07

FDA-CBER-2022-1614-2661202

US3542053
Folder: Safety Call Day 239 (1)
Form: Safety Call
Generated On: 10 Jun 2021 08:13:30
Please select one status for the follow-up contact

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Apr 2021 12:55:28
User entered 'Contact Made (CONTACT MADE)'	Madhu Balachandran (b) (4)	19 Apr 2021 18:41:07

US3542053
Folder: Safety Call Day 239 (1)
Form: Safety Call
Generated On: 10 Jun 2021 08:13:30
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Apr 2021 12:55:28
User entered empty.	Madhu Balachandran (b) (4)	19 Apr 2021 18:41:07

US3542053
Folder: Safety Call Day 239 (1)
Form: Continuing
Generated On: 10 Jun 2021 08:13:30
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Apr 2021 12:55:28
User entered 'Yes (Y)'	Madhu Balachandran (b) (4)	19 Apr 2021 18:41:12

US3542053
Folder: Safety Call Day 239 (1)
Form: Continuing
Generated On: 10 Jun 2021 08:13:30
Continuing Flag

Audit	User	Time (GMT)
User entered '1'	System	19 Apr 2021 18:41:12

US3542053
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 10 Jun 2021 08:13:30
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User signature succeeded.	David Diemert (b) (4) (b) (4)	13 Jan 2021 03:41:29
User entered 'Yes (Y)'	Erika Faust (b) (4) (b) (4)	08 Jan 2021 18:25:14

US3542053
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 10 Jun 2021 08:13:30
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User signature succeeded.	David Diemert (b) (4) (b) (4)	13 Jan 2021 03:41:29
User entered '08 Jan 2021'	Erika Faust (b) (4) (b) (4)	08 Jan 2021 18:25:14

US3542053
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 10 Jun 2021 08:13:30
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User signature succeeded.	David Diemert (b) (4) (b) (4)	13 Jan 2021 03:41:29
User entered 'Clinic (Clinic)'	Erika Faust (b) (4) (b) (4)	08 Jan 2021 18:25:14

US3542053
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 10 Jun 2021 08:13:30
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User entered 'UNBLND_DECIDE'	System	08 Jan 2021 18:25:14

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US3542053
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 08:13:30
Date of updated informed consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User signature succeeded.	David Diemert (b) (4) (b) (4)	13 Jan 2021 03:41:29
User entered '08 Jan 2021'	Erika Faust (b) (4) (b) (4)	08 Jan 2021 18:26:04

US3542053
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 08:13:30
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User signature succeeded.	David Diemert (b) (4) (b) (4)	12 Mar 2021 22:39:58
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 06:37:16

US3542053
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 08:13:30
Was the participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User signature succeeded.	David Diemert (b) (4) (b) (4)	13 Jan 2021 03:41:29
User entered 'Yes (Y)'	Erika Faust (b) (4) (b) (4)	08 Jan 2021 18:26:04

US3542053
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 08:13:30
Under what version of the Protocol was the Participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User signature succeeded.	David Diemert (b) (4) (b) (4)	12 Mar 2021 22:39:58
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 06:37:16

US3542053
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 08:13:30
Date of unblinding *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User signature succeeded.	David Diemert (b) (4) (b) (4)	13 Jan 2021 03:41:29
User entered '08 Jan 2021'	Erika Faust (b) (4) (b) (4)	08 Jan 2021 18:26:04

US3542053
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 08:13:30
Participant randomization assignment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User signature succeeded.	David Diemert (b) (4) (b) (4)	13 Jan 2021 03:41:29
User entered 'Placebo (Placebo)'	Erika Faust (b) (4) (b) (4)	08 Jan 2021 18:26:04

US3542053
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 08:13:30
Actual Dose 1

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 08:20:09
User signature succeeded.	David Diemert (b) (4) (b) (4)	13 Jan 2021 03:41:29
User entered 'Placebo (Placebo)'	Erika Faust (b) (4) (b) (4)	08 Jan 2021 18:26:04

FDA-CBER-2022-1614-2661217

US3542053
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 08:13:30
Actual Dose 2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 08:20:09
User signature succeeded.	David Diemert (b) (4) (b) (4)	13 Jan 2021 03:41:29
User entered 'Placebo (Placebo)'	Erika Faust (b) (4) (b) (4)	08 Jan 2021 18:26:04

FDA-CBER-2022-1614-2661218

US3542053
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 08:13:30
Will participant receive mRNA-1273?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User signature succeeded.	David Diemert (b) (4) (b) (4)	13 Jan 2021 03:41:29
User entered 'Yes (Y)'	Erika Faust (b) (4) (b) (4)	08 Jan 2021 18:26:04

US3542053
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 08:13:30
Placebo Only Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User entered '1'	System	08 Jan 2021 18:26:04

FDA-CBER-2022-1614-2661220

US3542053
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 08:13:30
Continuing with mRNA-1273

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User entered '1'	System	08 Jan 2021 18:26:04

FDA-CBER-2022-1614-2661221

US3542053
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 08:13:30
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User signature succeeded.	David Diemert (b) (4) (b) (4)	13 Jan 2021 03:41:29
User entered missing code ND - Not Done.	Erika Faust (b) (4) (b) (4)	08 Jan 2021 18:27:57

US3542053
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 08:13:30
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User signature succeeded.	David Diemert (b) (4) (b) (4)	13 Jan 2021 03:41:29
User entered missing code ND - Not Done.	Erika Faust (b) (4) (b) (4)	08 Jan 2021 18:27:57

US3542053
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 08:13:30
BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User entered empty.	System	08 Jan 2021 18:27:57
DataPoint set to visible.	System	08 Jan 2021 18:26:04

US3542053
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 08:13:30
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User signature succeeded.	David Diemert (b) (4) (b) (4)	13 Jan 2021 03:41:29
User entered missing code ND - Not Done.	Erika Faust (b) (4) (b) (4)	08 Jan 2021 18:27:57

US3542053
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 08:13:30
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User signature succeeded.	David Diemert (b) (4) (b) (4)	13 Jan 2021 03:41:29
User entered missing code ND - Not Done.	Erika Faust (b) (4) (b) (4)	08 Jan 2021 18:27:57

US3542053
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 08:13:30
BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User entered empty.	System	08 Jan 2021 18:27:57
DataPoint set to visible.	System	08 Jan 2021 18:26:04

US3542053
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 08:13:30
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User accepted default value 'Pre-Dose (PREDOSE)'	Erika Faust (b) (4) (b) (4)	08 Jan 2021 18:27:57

US3542053
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 08:13:30
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User signature succeeded.	David Diemert (b) (4) (b) (4)	13 Jan 2021 03:41:29
User entered 'Yes (Y)'	Erika Faust (b) (4) (b) (4)	08 Jan 2021 18:27:57

US3542053
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 08:13:30
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User signature succeeded.	David Diemert (b) (4) (b) (4)	13 Jan 2021 03:41:29
User entered '08 Jan 2021'	Erika Faust (b) (4) (b) (4)	08 Jan 2021 18:27:57

US3542053
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 08:13:30
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User signature succeeded.	David Diemert (b) (4) (b) (4)	13 Jan 2021 03:41:29
User entered '09:35'	Erika Faust (b) (4) (b) (4)	08 Jan 2021 18:27:57

US3542053
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 08:13:30
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User entered '08 Jan 2021 09:35'	System	08 Jan 2021 18:27:57

US3542053
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 08:13:30
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User signature succeeded.	David Diemert (b) (4) (b) (4)	13 Jan 2021 03:41:29
User entered '98.2' F	Erika Faust (b) (4) (b) (4)	08 Jan 2021 18:27:57

US3542053
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 08:13:30
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User signature succeeded.	David Diemert (b) (4) (b) (4)	13 Jan 2021 03:41:29
User entered 'Oral (Oral)'	Erika Faust (b) (4) (b) (4)	08 Jan 2021 18:27:57

US3542053
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 08:13:30
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User signature succeeded.	David Diemert (b) (4) (b) (4)	13 Jan 2021 03:41:29
User entered empty.	Erika Faust (b) (4) (b) (4)	08 Jan 2021 18:27:57

US3542053
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 08:13:30
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User signature succeeded.	David Diemert (b) (4) (b) (4)	13 Jan 2021 03:41:29
User entered '79'	Erika Faust (b) (4) (b) (4)	08 Jan 2021 18:27:57

US3542053
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 08:13:30
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User entered 'bpm'	System	08 Jan 2021 18:27:57

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US3542053
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 08:13:30
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User signature succeeded.	David Diemert (b) (4) (b) (4)	13 Jan 2021 03:41:29
User entered '16'	Erika Faust (b) (4) (b) (4)	08 Jan 2021 18:27:57

US3542053
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 08:13:30
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User entered 'breaths/min'	System	08 Jan 2021 18:27:57

US3542053
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 08:13:30
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User signature succeeded.	David Diemert (b) (4) (b) (4)	13 Jan 2021 03:41:29
User entered '133'	Erika Faust (b) (4) (b) (4)	08 Jan 2021 18:27:57

US3542053
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 08:13:30
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User entered 'mmHg'	System	08 Jan 2021 18:27:57

FDA-CBER-2022-1614-2661241

US3542053
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 08:13:30
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User signature succeeded.	David Diemert (b) (4) (b) (4)	13 Jan 2021 03:41:29
User entered '64'	Erika Faust (b) (4) (b) (4)	08 Jan 2021 18:27:57

US3542053
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 08:13:30
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User entered 'mmHg'	System	08 Jan 2021 18:27:57

FDA-CBER-2022-1614-2661243

US3542053
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 08:13:30
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User signature succeeded.	David Diemert (b) (4) (b) (4)	13 Jan 2021 03:41:29
User entered missing code ND - Not Done.	Erika Faust (b) (4) (b) (4)	08 Jan 2021 18:27:57

US3542053
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 08:13:30
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User signature succeeded.	David Diemert (b) (4) (b) (4)	13 Jan 2021 03:41:29
User entered missing code ND - Not Done.	Erika Faust (b) (4) (b) (4)	08 Jan 2021 18:27:57

US3542053
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 08:13:30
BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User entered empty.	System	08 Jan 2021 18:27:57
DataPoint set to visible.	System	08 Jan 2021 18:26:04

US3542053
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 08:13:30
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User accepted default value 'Post-Dose (POSTDOSE)'	Erika Faust (b) (4) (b) (4)	08 Jan 2021 18:27:57

FDA-CBER-2022-1614-2661247

US3542053
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 08:13:30
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User signature succeeded.	David Diemert (b) (4) (b) (4)	13 Jan 2021 03:41:29
User entered 'Yes (Y)'	Erika Faust (b) (4) (b) (4)	08 Jan 2021 18:27:57

US3542053
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 08:13:30
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User signature succeeded.	David Diemert (b) (4) (b) (4)	13 Jan 2021 03:41:29
User entered '08 Jan 2021'	Erika Faust (b) (4) (b) (4)	08 Jan 2021 18:27:57

FDA-CBER-2022-1614-2661249

US3542053
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 08:13:30
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User signature succeeded.	David Diemert (b) (4) (b) (4)	13 Jan 2021 03:41:29
User entered '10:25'	Erika Faust (b) (4) (b) (4)	08 Jan 2021 18:27:57

US3542053
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 08:13:30
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User entered '08 Jan 2021 10:25'	System	08 Jan 2021 18:27:57

US3542053
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 08:13:30
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User signature succeeded.	David Diemert (b) (4) (b) (4)	13 Jan 2021 03:41:29
User entered '98.2' F	Erika Faust (b) (4) (b) (4)	08 Jan 2021 18:27:57

US3542053
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 08:13:30
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User signature succeeded.	David Diemert (b) (4) (b) (4)	13 Jan 2021 03:41:29
User entered 'Oral (Oral)'	Erika Faust (b) (4) (b) (4)	08 Jan 2021 18:27:57

US3542053
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 08:13:30
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User signature succeeded.	David Diemert (b) (4) (b) (4)	13 Jan 2021 03:41:29
User entered empty.	Erika Faust (b) (4) (b) (4)	08 Jan 2021 18:27:57

US3542053
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 08:13:30
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User signature succeeded.	David Diemert (b) (4) (b) (4)	13 Jan 2021 03:41:29
User entered '78'	Erika Faust (b) (4) (b) (4)	08 Jan 2021 18:27:57

US3542053
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 08:13:30
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User entered 'bpm'	System	08 Jan 2021 18:27:57

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US3542053
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 08:13:30
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User signature succeeded.	David Diemert (b) (4) (b) (4)	13 Jan 2021 03:41:29
User entered '16'	Erika Faust (b) (4) (b) (4)	08 Jan 2021 18:27:57

US3542053
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 08:13:30
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User entered 'breaths/min'	System	08 Jan 2021 18:27:57

FDA-CBER-2022-1614-2661258

US3542053
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 08:13:30
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User signature succeeded.	David Diemert (b) (4) (b) (4)	13 Jan 2021 03:41:29
User entered '114'	Erika Faust (b) (4) (b) (4)	08 Jan 2021 18:27:57

US3542053
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 08:13:30
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User entered 'mmHg'	System	08 Jan 2021 18:27:57

FDA-CBER-2022-1614-2661260

US3542053
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 08:13:30
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User signature succeeded.	David Diemert (b) (4) (b) (4)	13 Jan 2021 03:41:29
User entered '80'	Erika Faust (b) (4) (b) (4)	08 Jan 2021 18:27:57

US3542053
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 08:13:30
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User entered 'mmHg'	System	08 Jan 2021 18:27:57

FDA-CBER-2022-1614-2661262

US3542053
Folder: Participant Decision Visit / OL-D1 (1)
Form: Physical Examination
Generated On: 10 Jun 2021 08:13:30
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User signature succeeded.	David Diemert (b) (4) (b) (4)	13 Jan 2021 03:41:29
User entered 'Yes (Y)'	Erika Faust (b) (4) (b) (4)	08 Jan 2021 18:26:31

FDA-CBER-2022-1614-2661263

US3542053
Folder: Participant Decision Visit / OL-D1 (1)
Form: Physical Examination
Generated On: 10 Jun 2021 08:13:30
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User signature succeeded.	David Diemert (b) (4) (b) (4)	13 Jan 2021 03:41:29
User entered '08 Jan 2021'	Erika Faust (b) (4) (b) (4)	08 Jan 2021 18:26:31

FDA-CBER-2022-1614-2661264

US3542053
Folder: Participant Decision Visit / OL-D1 (1)
Form: Exposure
Generated On: 10 Jun 2021 08:13:30
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User signature succeeded.	David Diemert (b) (4) (b) (4)	13 Jan 2021 03:41:29
User entered 'Yes (Y)'	Erika Faust (b) (4) (b) (4)	08 Jan 2021 18:26:54

US3542053
Folder: Participant Decision Visit / OL-D1 (1)
Form: Exposure
Generated On: 10 Jun 2021 08:13:30
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User signature succeeded.	David Diemert (b) (4) (b) (4)	13 Jan 2021 03:41:29
User entered empty.	Erika Faust (b) (4) (b) (4)	08 Jan 2021 18:26:54

US3542053
Folder: Participant Decision Visit / OL-D1 (1)
Form: Exposure
Generated On: 10 Jun 2021 08:13:30
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User signature succeeded.	David Diemert (b) (4) (b) (4)	13 Jan 2021 03:41:29
User entered empty.	Erika Faust (b) (4) (b) (4)	08 Jan 2021 18:26:54

US3542053
Folder: Participant Decision Visit / OL-D1 (1)
Form: Exposure
Generated On: 10 Jun 2021 08:13:30
What was the study treatment? (Unblinded)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User entered 'mRNA-1273'	System	08 Jan 2021 18:26:54
DataPoint set to visible.	System	08 Jan 2021 18:26:04

US3542053
Folder: Participant Decision Visit / OL-D1 (1)
Form: Exposure
Generated On: 10 Jun 2021 08:13:30
What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User signature succeeded.	David Diemert (b) (4) (b) (4)	13 Jan 2021 03:41:29
User entered '08 Jan 2021'	Erika Faust (b) (4) (b) (4)	08 Jan 2021 18:26:54

US3542053
Folder: Participant Decision Visit / OL-D1 (1)
Form: Exposure
Generated On: 10 Jun 2021 08:13:30
What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User signature succeeded.	David Diemert (b) (4) (b) (4)	13 Jan 2021 03:41:29
User entered '09:55'	Erika Faust (b) (4) (b) (4)	08 Jan 2021 18:26:54

US3542053
Folder: Participant Decision Visit / OL-D1 (1)
Form: Exposure
Generated On: 10 Jun 2021 08:13:30
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User entered '08 Jan 2021 09:55'	System	08 Jan 2021 18:26:54

US3542053
Folder: Participant Decision Visit / OL-D1 (1)
Form: Exposure
Generated On: 10 Jun 2021 08:13:30
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User signature succeeded.	David Diemert (b) (4) (b) (4)	13 Jan 2021 03:41:29
User entered 'Left Arm (LEFT ARM)'	Erika Faust (b) (4) (b) (4)	08 Jan 2021 18:26:54

US3542053
Folder: Participant Decision Visit / OL-D1 (1)
Form: Exposure
Generated On: 10 Jun 2021 08:13:30
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User entered 'ONCE'	System	08 Jan 2021 18:26:54

US3542053
Folder: Participant Decision Visit / OL-D1 (1)
Form: Exposure
Generated On: 10 Jun 2021 08:13:30
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User entered 'INTRAMUSCULAR'	System	08 Jan 2021 18:26:54

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US3542053
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 08:13:30
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User signature succeeded.	David Diemert (b) (4) (b) (4)	13 Jan 2021 03:41:29
User entered 'Yes (Y)'	Erika Faust (b) (4) (b) (4)	08 Jan 2021 18:25:27

US3542053
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 08:13:30
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User signature succeeded.	David Diemert (b) (4) (b) (4)	13 Jan 2021 03:41:29
User entered '08 Jan 2021'	Erika Faust (b) (4) (b) (4)	08 Jan 2021 18:25:27

US3542053
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 08:13:30
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User signature succeeded.	David Diemert (b) (4) (b) (4)	13 Jan 2021 03:41:29
User entered '09:45'	Erika Faust (b) (4) (b) (4)	08 Jan 2021 18:25:27

US3542053
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 08:13:30
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User entered '08 Jan 2021 09:45'	System	08 Jan 2021 18:25:27

FDA-CBER-2022-1614-2661278

US3542053
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 10 Jun 2021 08:13:30
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User signature succeeded.	David Diemert (b) (4) (b) (4)	13 Jan 2021 03:41:29
User entered 'Yes (Y)'	Erika Faust (b) (4) (b) (4)	08 Jan 2021 18:25:41

US3542053
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 10 Jun 2021 08:13:30
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User signature succeeded.	David Diemert (b) (4) (b) (4)	13 Jan 2021 03:41:29
User entered '08 Jan 2021'	Erika Faust (b) (4) (b) (4)	08 Jan 2021 18:25:41

US3542053
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 10 Jun 2021 08:13:30
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User signature succeeded.	David Diemert (b) (4) (b) (4)	13 Jan 2021 03:41:29
User entered '09:51'	Erika Faust (b) (4) (b) (4)	08 Jan 2021 18:25:41

US3542053
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 10 Jun 2021 08:13:30
Collection Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User entered '08 Jan 2021 09:51'	System	08 Jan 2021 18:25:41

FDA-CBER-2022-1614-2661282

US3542053
Folder: Participant Decision Visit / OL-D1 (1)
Form: Continuing
Generated On: 10 Jun 2021 08:13:30
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User signature succeeded.	David Diemert (b) (4) (b) (4)	13 Jan 2021 03:41:29
User entered 'Yes (Y)'	Erika Faust (b) (4) (b) (4)	08 Jan 2021 18:26:35

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US3542053
Folder: Participant Decision Visit / OL-D1 (1)
Form: Continuing
Generated On: 10 Jun 2021 08:13:30
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User entered '1'	System	08 Jan 2021 18:26:35

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US3542053
Folder: Safety Call OL-D8 (1)
Form: Safety Call
Generated On: 10 Jun 2021 08:13:30
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User signature succeeded.	David Diemert (b) (4) (b) (4)	22 Jan 2021 18:10:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Jan 2021 17:36:29

US3542053
Folder: Safety Call OL-D8 (1)
Form: Safety Call
Generated On: 10 Jun 2021 08:13:30
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User signature succeeded.	David Diemert (b) (4) (b) (4)	22 Jan 2021 18:10:54
User entered '15 Jan 2021'	(b) (4), (b) (6)	21 Jan 2021 17:36:29

US3542053
Folder: Safety Call OL-D8 (1)
Form: Safety Call
Generated On: 10 Jun 2021 08:13:30
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User signature succeeded.	David Diemert (b) (4) (b) (4)	22 Jan 2021 18:10:54
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	21 Jan 2021 17:36:29

US3542053
Folder: Safety Call OL-D8 (1)
Form: Safety Call
Generated On: 10 Jun 2021 08:13:30
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User signature succeeded.	David Diemert (b) (4) (b) (4)	22 Jan 2021 18:10:54
User entered empty.	(b) (4), (b) (6)	21 Jan 2021 17:36:29

US3542053
Folder: Safety Call OL-D8 (1)
Form: Continuing
Generated On: 10 Jun 2021 08:13:30
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User signature succeeded.	David Diemert (b) (4) (b) (4)	22 Jan 2021 18:10:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Jan 2021 17:36:42

US3542053
Folder: Safety Call OL-D8 (1)
Form: Continuing
Generated On: 10 Jun 2021 08:13:30
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User entered '1'	System	21 Jan 2021 17:36:42

US3542053
Folder: Safety Call OL-D8 (1)
Form: Continuing
Generated On: 10 Jun 2021 08:13:30
OLD29 Placebo Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User entered '1'	System	21 Jan 2021 17:36:42
DataPoint set to visible.	System	21 Jan 2021 17:36:42

US3542053
Folder: OL-D29 (1)
Form: Visit Date
Generated On: 10 Jun 2021 08:13:30
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Mar 2021 14:54:22
User entered 'Yes (Y)'	Erika Faust (b) (4) (b) (4)	26 Feb 2021 16:32:10

US3542053
Folder: OL-D29 (1)
Form: Visit Date
Generated On: 10 Jun 2021 08:13:30
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Mar 2021 14:54:22
User closed query 'OL-D29 Visit Date is < 25 days or > 42 days after the Participant Decision visit vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	05 Mar 2021 08:28:13
Query 'OL-D29 Visit Date is < 25 days or > 42 days after the Participant Decision visit vaccination. Please reconcile or confirm dates.' answered with 'Participant had a confirmed case of symptomatic COVID-19. OL-1 vaccination #1 was delayed due to this.' (Site from System).	David Diemert (b) (4) (b) (4)	03 Mar 2021 20:42:26
User opened query 'OL-D29 Visit Date is < 25 days or > 42 days after the Participant Decision visit vaccination. Please reconcile or confirm dates.' (Site from System).	System	26 Feb 2021 16:32:10
User entered '25 Feb 2021'	Erika Faust (b) (4) (b) (4)	26 Feb 2021 16:32:10

US3542053
Folder: OL-D29 (1)
Form: Visit Date
Generated On: 10 Jun 2021 08:13:30
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Mar 2021 14:54:22
User entered 'Clinic (Clinic)'	Erika Faust (b) (4) (b) (4)	26 Feb 2021 16:32:10

US3542053
Folder: OL-D29 (1)
Form: Visit Date
Generated On: 10 Jun 2021 08:13:30
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User entered 'OLD29'	System	26 Feb 2021 16:32:10

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US3542053
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 08:13:30
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User accepted default value 'Pre-Dose (PREDOSE)'	Erika Faust (b) (4) (b) (4)	26 Feb 2021 16:33:52

FDA-CBER-2022-1614-2661296

US3542053
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 08:13:30
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Mar 2021 14:54:22
User entered 'Yes (Y)'	Erika Faust (b) (4) (b) (4)	26 Feb 2021 16:33:52

US3542053
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 08:13:30
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Mar 2021 14:54:22
User entered '25 Feb 2021'	Erika Faust (b) (4) (b) (4)	26 Feb 2021 16:33:52

US3542053
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 08:13:30
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Mar 2021 14:54:22
User entered '09:19'	Erika Faust (b) (4) (b) (4)	26 Feb 2021 16:33:52

US3542053
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 08:13:30
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User entered '25 Feb 2021 09:19'	System	26 Feb 2021 16:33:52

FDA-CBER-2022-1614-2661300

US3542053
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 08:13:30
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Mar 2021 14:54:22
User entered '98.0' F	Erika Faust (b) (4) (b) (4)	26 Feb 2021 16:33:52

US3542053
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 08:13:30
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Mar 2021 14:54:22
User entered 'Oral (Oral)'	Erika Faust (b) (4) (b) (4)	26 Feb 2021 16:33:52

FDA-CBER-2022-1614-2661302

US3542053
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 08:13:30
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Mar 2021 14:54:22
User entered empty.	Erika Faust (b) (4) (b) (4)	26 Feb 2021 16:33:52

FDA-CBER-2022-1614-2661303

US3542053
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 08:13:30
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Mar 2021 14:54:22
User entered '55'	Erika Faust (b) (4) (b) (4)	26 Feb 2021 16:33:52

US3542053
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 08:13:30
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User entered 'bpm'	System	26 Feb 2021 16:33:52

FDA-CBER-2022-1614-2661305

US3542053
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 08:13:30
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Mar 2021 14:54:22
User entered '18'	Erika Faust (b) (4) (b) (4)	26 Feb 2021 16:33:52

US3542053
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 08:13:30
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User entered 'breaths/min'	System	26 Feb 2021 16:33:52

FDA-CBER-2022-1614-2661307

US3542053
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 08:13:30
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Mar 2021 14:54:22
User entered '115'	Erika Faust (b) (4) (b) (4)	26 Feb 2021 16:33:52

US3542053
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 08:13:30
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User entered 'mmHg'	System	26 Feb 2021 16:33:52

FDA-CBER-2022-1614-2661309

US3542053
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 08:13:30
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Mar 2021 14:54:22
User entered '64'	Erika Faust (b) (4) (b) (4)	26 Feb 2021 16:33:52

US3542053
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 08:13:30
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User entered 'mmHg'	System	26 Feb 2021 16:33:52

FDA-CBER-2022-1614-2661311

US3542053
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 08:13:30
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User accepted default value 'Post-Dose (POSTDOSE)'	Erika Faust (b) (4) (b) (4)	26 Feb 2021 16:33:52

FDA-CBER-2022-1614-2661312

US3542053
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 08:13:30
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Mar 2021 14:54:22
User entered 'Yes (Y)'	Erika Faust (b) (4) (b) (4)	26 Feb 2021 16:33:52

US3542053
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 08:13:30
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Mar 2021 14:54:22
User entered '25 Feb 2021'	Erika Faust (b) (4) (b) (4)	26 Feb 2021 16:33:52

US3542053
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 08:13:30
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Mar 2021 14:54:22
User entered '10:25'	Erika Faust (b) (4) (b) (4)	26 Feb 2021 16:33:52

US3542053
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 08:13:30
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User entered '25 Feb 2021 10:25'	System	26 Feb 2021 16:33:52

FDA-CBER-2022-1614-2661316

US3542053
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 08:13:30
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Mar 2021 14:54:22
User entered '98.2' F	Erika Faust (b) (4) (b) (4)	26 Feb 2021 16:33:52

US3542053
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 08:13:30
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Mar 2021 14:54:22
User entered 'Oral (Oral)'	Erika Faust (b) (4) (b) (4)	26 Feb 2021 16:33:52

FDA-CBER-2022-1614-2661318

US3542053
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 08:13:30
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Mar 2021 14:54:22
User entered empty.	Erika Faust (b) (4) (b) (4)	26 Feb 2021 16:33:52

US3542053
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 08:13:30
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Mar 2021 14:54:22
User entered '53'	Erika Faust (b) (4) (b) (4)	26 Feb 2021 16:33:52

US3542053
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 08:13:30
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User entered 'bpm'	System	26 Feb 2021 16:33:52

FDA-CBER-2022-1614-2661321

US3542053
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 08:13:30
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Mar 2021 14:54:22
User entered '16'	Erika Faust (b) (4) (b) (4)	26 Feb 2021 16:33:52

US3542053
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 08:13:30
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User entered 'breaths/min'	System	26 Feb 2021 16:33:52

FDA-CBER-2022-1614-2661323

US3542053
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 08:13:30
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Mar 2021 14:54:22
User entered '120'	Erika Faust (b) (4) (b) (4)	26 Feb 2021 16:33:52

FDA-CBER-2022-1614-2661324

US3542053
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 08:13:30
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User entered 'mmHg'	System	26 Feb 2021 16:33:52

FDA-CBER-2022-1614-2661325

US3542053
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 08:13:30
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Mar 2021 14:54:22
User entered '65'	Erika Faust (b) (4) (b) (4)	26 Feb 2021 16:33:52

US3542053
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 08:13:30
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User entered 'mmHg'	System	26 Feb 2021 16:33:52

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US3542053
Folder: OL-D29 (1)
Form: Physical Examination
Generated On: 10 Jun 2021 08:13:30
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Mar 2021 14:54:22
User entered 'Yes (Y)'	Erika Faust (b) (4) (b) (4)	26 Feb 2021 16:32:29

US3542053
Folder: OL-D29 (1)
Form: Physical Examination
Generated On: 10 Jun 2021 08:13:30
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Mar 2021 14:54:22
User entered '25 Feb 2021'	Erika Faust (b) (4) (b) (4)	26 Feb 2021 16:32:29

US3542053
Folder: OL-D29 (1)
Form: Exposure
Generated On: 10 Jun 2021 08:13:30
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Mar 2021 14:54:22
User entered 'Yes (Y)'	Erika Faust (b) (4) (b) (4)	26 Feb 2021 16:32:48

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US3542053
Folder: OL-D29 (1)
Form: Exposure
Generated On: 10 Jun 2021 08:13:30
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Mar 2021 14:54:22
User entered empty.	Erika Faust (b) (4) (b) (4)	26 Feb 2021 16:32:48

US3542053
Folder: OL-D29 (1)
Form: Exposure
Generated On: 10 Jun 2021 08:13:30
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Mar 2021 14:54:22
User entered empty.	Erika Faust (b) (4) (b) (4)	26 Feb 2021 16:32:48

US3542053
Folder: OL-D29 (1)
Form: Exposure
Generated On: 10 Jun 2021 08:13:30
What was the study treatment? (Unblinded)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User entered 'mRNA-1273'	System	26 Feb 2021 16:32:48
DataPoint set to visible.	System	21 Jan 2021 17:36:42

US3542053
Folder: OL-D29 (1)
Form: Exposure
Generated On: 10 Jun 2021 08:13:30
What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Mar 2021 14:54:22
User entered '25 Feb 2021'	Erika Faust (b) (4) (b) (4)	26 Feb 2021 16:32:48

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US3542053
Folder: OL-D29 (1)
Form: Exposure
Generated On: 10 Jun 2021 08:13:30
What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Mar 2021 14:54:22
User entered '09:55'	Erika Faust (b) (4) (b) (4)	26 Feb 2021 16:32:48

FDA-CBER-2022-1614-2661335

US3542053
Folder: OL-D29 (1)
Form: Exposure
Generated On: 10 Jun 2021 08:13:30
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User entered '25 Feb 2021 09:55'	System	26 Feb 2021 16:32:48

US3542053
Folder: OL-D29 (1)
Form: Exposure
Generated On: 10 Jun 2021 08:13:30
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Mar 2021 14:54:22
User entered 'Left Arm (LEFT ARM)'	Erika Faust (b) (4) (b) (4)	26 Feb 2021 16:32:48

US3542053
Folder: OL-D29 (1)
Form: Exposure
Generated On: 10 Jun 2021 08:13:30
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User entered 'ONCE'	System	26 Feb 2021 16:32:48

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US3542053
Folder: OL-D29 (1)
Form: Exposure
Generated On: 10 Jun 2021 08:13:30
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User entered 'INTRAMUSCULAR'	System	26 Feb 2021 16:32:48

FDA-CBER-2022-1614-2661339

US3542053
Folder: OL-D29 (1)
Form: Continuing
Generated On: 10 Jun 2021 08:13:30
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Mar 2021 14:54:22
User entered 'Yes (Y)'	Erika Faust (b) (4) (b) (4)	26 Feb 2021 16:32:34

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US3542053
Folder: OL-D29 (1)
Form: Continuing
Generated On: 10 Jun 2021 08:13:30
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User entered '1'	System	26 Feb 2021 16:32:34

FDA-CBER-2022-1614-2661341

US3542053
Folder: Safety Call OL-D36 (1)
Form: Safety Call
Generated On: 10 Jun 2021 08:13:30
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User signature succeeded.	David Diemert (b) (4) (b) (4)	09 Mar 2021 04:08:47
User entered 'Yes (Y)'	Erika Faust (b) (4) (b) (4)	08 Mar 2021 19:33:39

FDA-CBER-2022-1614-2661342

US3542053
Folder: Safety Call OL-D36 (1)
Form: Safety Call
Generated On: 10 Jun 2021 08:13:30
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User signature succeeded.	David Diemert (b) (4) (b) (4)	09 Mar 2021 04:08:47
User entered '05 Mar 2021'	Erika Faust (b) (4) (b) (4)	08 Mar 2021 19:33:39

FDA-CBER-2022-1614-2661343

US3542053
Folder: Safety Call OL-D36 (1)
Form: Safety Call
Generated On: 10 Jun 2021 08:13:30
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User signature succeeded.	David Diemert (b) (4) (b) (4)	09 Mar 2021 04:08:47
User entered 'Contact Made (CONTACT MADE)'	Erika Faust (b) (4) (b) (4)	08 Mar 2021 19:33:39

FDA-CBER-2022-1614-2661344

US3542053
Folder: Safety Call OL-D36 (1)
Form: Safety Call
Generated On: 10 Jun 2021 08:13:30
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User signature succeeded.	David Diemert (b) (4) (b) (4)	09 Mar 2021 04:08:47
User entered empty.	Erika Faust (b) (4) (b) (4)	08 Mar 2021 19:33:39

US3542053
Folder: Safety Call OL-D36 (1)
Form: Continuing
Generated On: 10 Jun 2021 08:13:30
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User signature succeeded.	David Diemert (b) (4) (b) (4)	09 Mar 2021 04:08:47
User entered 'Yes (Y)'	Erika Faust (b) (4) (b) (4)	08 Mar 2021 19:33:44

US3542053
Folder: Safety Call OL-D36 (1)
Form: Continuing
Generated On: 10 Jun 2021 08:13:30
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User entered '1'	System	08 Mar 2021 19:33:44

FDA-CBER-2022-1614-2661347

US3542053
Folder: OL-D57 (1)
Form: Visit Date
Generated On: 10 Jun 2021 08:13:30
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 17:35:54
User signature succeeded.	David Diemert (b) (4) (b) (4)	26 Mar 2021 16:51:28
User entered 'Yes (Y)'	Erika Faust (b) (4) (b) (4)	25 Mar 2021 18:03:04

FDA-CBER-2022-1614-2661348

US3542053
Folder: OL-D57 (1)
Form: Visit Date
Generated On: 10 Jun 2021 08:13:30
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 17:35:54
User signature succeeded.	David Diemert (b) (4) (b) (4)	26 Mar 2021 16:51:28
User entered '24 Mar 2021'	Erika Faust (b) (4) (b) (4)	25 Mar 2021 18:03:04

FDA-CBER-2022-1614-2661349

US3542053
Folder: OL-D57 (1)
Form: Visit Date
Generated On: 10 Jun 2021 08:13:30
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 17:35:54
User signature succeeded.	David Diemert (b) (4) (b) (4)	26 Mar 2021 16:51:28
User entered 'Clinic (Clinic)'	Erika Faust (b) (4) (b) (4)	25 Mar 2021 18:03:04

US3542053
Folder: OL-D57 (1)
Form: Visit Date
Generated On: 10 Jun 2021 08:13:30
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User entered 'OLD57'	System	25 Mar 2021 18:03:04

FDA-CBER-2022-1614-2661351

US3542053
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 08:13:30
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 17:35:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	26 Mar 2021 16:51:28
User entered 'No (N)'	Erika Faust (b) (4) (b) (4)	25 Mar 2021 18:03:11

US3542053
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 08:13:30
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 17:35:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	26 Mar 2021 16:51:28
User entered empty.	Erika Faust (b) (4) (b) (4)	25 Mar 2021 18:03:11

FDA-CBER-2022-1614-2661353

US3542053
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 08:13:30
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 17:35:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	26 Mar 2021 16:51:28
User entered empty.	Erika Faust (b) (4) (b) (4)	25 Mar 2021 18:03:11

US3542053
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 08:13:30
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User entered empty.	System	25 Mar 2021 18:03:11

FDA-CBER-2022-1614-2661355

US3542053
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 08:13:30
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 17:35:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	26 Mar 2021 16:51:28
User entered empty.	Erika Faust (b) (4) (b) (4)	25 Mar 2021 18:03:11

FDA-CBER-2022-1614-2661356

US3542053
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 08:13:30
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 17:35:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	26 Mar 2021 16:51:28
User entered empty.	Erika Faust (b) (4) (b) (4)	25 Mar 2021 18:03:11

US3542053
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 08:13:30
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 17:35:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	26 Mar 2021 16:51:28
User entered empty.	Erika Faust (b) (4) (b) (4)	25 Mar 2021 18:03:11

US3542053
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 08:13:30
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 17:35:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	26 Mar 2021 16:51:28
User entered empty.	Erika Faust (b) (4) (b) (4)	25 Mar 2021 18:03:11

US3542053
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 08:13:30
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User entered empty.	System	25 Mar 2021 18:03:11

US3542053
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 08:13:30
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 17:35:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	26 Mar 2021 16:51:28
User entered empty.	Erika Faust (b) (4) (b) (4)	25 Mar 2021 18:03:11

FDA-CBER-2022-1614-2661361

US3542053
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 08:13:30
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User entered empty.	System	25 Mar 2021 18:03:11

US3542053
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 08:13:30
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 17:35:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	26 Mar 2021 16:51:28
User entered empty.	Erika Faust (b) (4) (b) (4)	25 Mar 2021 18:03:11

FDA-CBER-2022-1614-2661363

US3542053
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 08:13:30
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User entered empty.	System	25 Mar 2021 18:03:11

FDA-CBER-2022-1614-2661364

US3542053
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 08:13:30
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 17:35:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	26 Mar 2021 16:51:28
User entered empty.	Erika Faust (b) (4) (b) (4)	25 Mar 2021 18:03:11

FDA-CBER-2022-1614-2661365

US3542053
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 08:13:30
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User entered empty.	System	25 Mar 2021 18:03:11

FDA-CBER-2022-1614-2661366

US3542053
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 08:13:30
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55

FDA-CBER-2022-1614-2661367

US3542053
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 08:13:30
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55

FDA-CBER-2022-1614-2661368

US3542053
Folder: OL-D57 (1)
Form: Physical Examination
Generated On: 10 Jun 2021 08:13:30
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 17:36:03
User signature succeeded.	David Diemert (b) (4) (b) (4)	26 Mar 2021 16:51:28
User entered 'No (N)'	Erika Faust (b) (4) (b) (4)	25 Mar 2021 18:03:17

US3542053
Folder: OL-D57 (1)
Form: Physical Examination
Generated On: 10 Jun 2021 08:13:30
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 17:36:03
User signature succeeded.	David Diemert (b) (4) (b) (4)	26 Mar 2021 16:51:28
User entered empty.	Erika Faust (b) (4) (b) (4)	25 Mar 2021 18:03:17

US3542053
Folder: OL-D57 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 08:13:30
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 17:36:07
User signature succeeded.	David Diemert (b) (4) (b) (4)	26 Mar 2021 16:51:28
User entered 'Yes (Y)'	Erika Faust (b) (4) (b) (4)	25 Mar 2021 18:03:32

US3542053
Folder: OL-D57 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 08:13:30
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 17:36:07
User signature succeeded.	David Diemert (b) (4) (b) (4)	26 Mar 2021 16:51:28
User entered '24 Mar 2021'	Erika Faust (b) (4) (b) (4)	25 Mar 2021 18:03:32

US3542053
Folder: OL-D57 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 08:13:30
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 17:36:07
User signature succeeded.	David Diemert (b) (4) (b) (4)	26 Mar 2021 16:51:28
User entered '09:03'	Erika Faust (b) (4) (b) (4)	25 Mar 2021 18:03:32

US3542053
Folder: OL-D57 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 08:13:30
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:55:55
User entered '24 Mar 2021 09:03'	System	25 Mar 2021 18:03:32

US3542053
Folder: Adverse Events
Form: Adverse Events Summary
Generated On: 10 Jun 2021 08:13:30
Did the participant experience any adverse events?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:47:56
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:18:25
User signature succeeded.	David Diemert (b) (4) (b) (4)	30 Sep 2020 22:38:17
User entered 'Yes (Y)'	DeEnna Wedding (b) (4) (b) (4)	30 Sep 2020 18:37:37

US3542053
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 08:13:30
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:39

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US3542053
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 08:13:30
Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	30 Sep 2020 22:38:17
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Low back pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Sep 2020 18:40:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Sep 2020 18:40:51
Data point term sent to Coder	System	30 Sep 2020 18:39:43
User entered 'back pain, lower'	DeEnna Wedding (b) (4) (b) (4)	30 Sep 2020 18:39:31

US3542053
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 08:13:30
Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	30 Sep 2020 22:38:17
User entered 'Yes (Y)'	DeEnna Wedding (b) (4) (b) (4)	30 Sep 2020 18:39:31

US3542053
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 08:13:30
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	30 Sep 2020 22:38:17
User entered 'No (N)'	DeEnna Wedding (b) (4) (b) (4)	30 Sep 2020 18:39:31

US3542053
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 08:13:30
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	30 Sep 2020 22:38:17
User entered 'No (N)'	DeEnna Wedding (b) (4) (b) (4)	30 Sep 2020 18:39:31

US3542053
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 08:13:30
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	30 Sep 2020 22:38:17
User entered '25 Sep 2020'	DeEnna Wedding (b) (4) (b) (4)	30 Sep 2020 18:39:31

FDA-CBER-2022-1614-2661381

US3542053
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 08:13:30
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	30 Sep 2020 22:38:17
User entered empty.	DeEnna Wedding (b) (4) (b) (4)	30 Sep 2020 18:39:31

US3542053
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 08:13:30
AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:39
User entered empty.	System	30 Sep 2020 18:39:31

US3542053
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 08:13:30
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Oct 2020 18:32:30
Signature has been broken.	Erika Faust (b) (4) (b) (4)	21 Oct 2020 16:07:32
User entered 'No (N)' reason for change: New Information	Erika Faust (b) (4) (b) (4)	21 Oct 2020 16:07:32
User signature succeeded.	David Diemert (b) (4) (b) (4)	30 Sep 2020 22:38:17
User entered 'Yes (Y)'	DeEnna Wedding (b) (4) (b) (4)	30 Sep 2020 18:39:31

US3542053
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 08:13:30
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Oct 2020 18:32:30
Signature has been broken.	Erika Faust (b) (4) (b) (4)	21 Oct 2020 16:07:32
User entered '2 Oct 2020' reason for change: New Information	Erika Faust (b) (4) (b) (4)	21 Oct 2020 16:07:32
User signature succeeded.	David Diemert (b) (4) (b) (4)	30 Sep 2020 22:38:17
User entered empty.	DeEnna Wedding (b) (4) (b) (4)	30 Sep 2020 18:39:31

FDA-CBER-2022-1614-2661385

US3542053
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 08:13:30
End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	30 Sep 2020 22:38:17
User entered empty.	DeEnna Wedding (b) (4) (b) (4)	30 Sep 2020 18:39:31

US3542053
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 08:13:30
AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:39
User entered empty.	System	30 Sep 2020 18:39:31

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US3542053
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 08:13:30
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	30 Sep 2020 22:38:17
User entered 'Grade 3/Severe (Grade 3/Severe)'	DeEnna Wedding (b) (4) (b) (4)	30 Sep 2020 18:39:31

US3542053
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 08:13:30
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	30 Sep 2020 22:38:17
User entered 'No (N)'	DeEnna Wedding (b) (4) (b) (4)	30 Sep 2020 18:39:31

US3542053
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 08:13:30
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	30 Sep 2020 22:38:17
User entered '0'	DeEnna Wedding (b) (4) (b) (4)	30 Sep 2020 18:39:31

US3542053
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 08:13:30
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	30 Sep 2020 22:38:17
User entered '0'	DeEnna Wedding (b) (4) (b) (4)	30 Sep 2020 18:39:31

US3542053
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 08:13:30
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	30 Sep 2020 22:38:17
User entered '0'	DeEnna Wedding (b) (4) (b) (4)	30 Sep 2020 18:39:31

US3542053
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 08:13:30
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	30 Sep 2020 22:38:17
User entered empty.	DeEnna Wedding (b) (4) (b) (4)	30 Sep 2020 18:39:31

US3542053
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 08:13:30
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	30 Sep 2020 22:38:17
User entered empty.	DeEnna Wedding (b) (4) (b) (4)	30 Sep 2020 18:39:31

US3542053
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 08:13:30
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	30 Sep 2020 22:38:17
User entered empty.	DeEnna Wedding (b) (4) (b) (4)	30 Sep 2020 18:39:31

US3542053
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 08:13:30
Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	30 Sep 2020 22:38:17
User entered empty.	DeEnna Wedding (b) (4) (b) (4)	30 Sep 2020 18:39:31

US3542053
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 08:13:30
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	30 Sep 2020 22:38:17
User entered '0'	DeEnna Wedding (b) (4) (b) (4)	30 Sep 2020 18:39:31

US3542053
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 08:13:30
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	30 Sep 2020 22:38:17
User entered '0'	DeEnna Wedding (b) (4) (b) (4)	30 Sep 2020 18:39:31

US3542053
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 08:13:30
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	30 Sep 2020 22:38:17
User entered '0'	DeEnna Wedding (b) (4) (b) (4)	30 Sep 2020 18:39:31

US3542053
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 08:13:30
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	30 Sep 2020 22:38:17
User entered 'Not Related (NOT RELATED)'	DeEnna Wedding (b) (4) (b) (4)	30 Sep 2020 18:39:31

US3542053
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 08:13:30
Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	30 Sep 2020 22:38:17
User entered 'Not Related (NOT RELATED)'	DeEnna Wedding (b) (4) (b) (4)	30 Sep 2020 18:39:31

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US3542053
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 08:13:30
Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	30 Sep 2020 22:38:17
User entered 'None (NONE)'	DeEnna Wedding (b) (4) (b) (4)	30 Sep 2020 18:39:31

US3542053
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 08:13:30
None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	30 Sep 2020 22:38:17
User entered '0'	DeEnna Wedding (b) (4) (b) (4)	30 Sep 2020 18:39:31

US3542053
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 08:13:30
Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	30 Sep 2020 22:38:17
User entered '1'	DeEnna Wedding (b) (4) (b) (4)	30 Sep 2020 18:39:31

US3542053
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 08:13:30
Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	30 Sep 2020 22:38:17
User entered '0'	DeEnna Wedding (b) (4) (b) (4)	30 Sep 2020 18:39:31

US3542053
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 08:13:30
Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Oct 2020 18:32:30
Signature has been broken.	Erika Faust (b) (4) (b) (4)	21 Oct 2020 16:07:32
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Erika Faust (b) (4) (b) (4)	21 Oct 2020 16:07:32
User signature succeeded.	David Diemert (b) (4) (b) (4)	30 Sep 2020 22:38:17
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	DeEnna Wedding (b) (4) (b) (4)	30 Sep 2020 18:39:31

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US3542053
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 08:13:30
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	30 Sep 2020 22:38:17
User entered empty.	DeEnna Wedding (b) (4) (b) (4)	30 Sep 2020 18:39:31

US3542053
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 08:13:30
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:39
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	30 Sep 2020 22:38:17
User entered empty.	DeEnna Wedding (b) (4) (b) (4)	30 Sep 2020 18:39:31

FDA-CBER-2022-1614-2661408

US3542053
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 08:13:30
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:39
User entered '0'	System	30 Sep 2020 18:39:31

US3542053
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 08:13:30
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:39
User entered '1'	System	30 Sep 2020 18:39:31

US3542053
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 08:13:30
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:39

FDA-CBER-2022-1614-2661411

US3542053
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 08:13:30
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:41

FDA-CBER-2022-1614-2661412

US3542053
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 08:13:30
Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:41
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Oct 2020 18:32:30
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Neurological signs and symptoms NEC, PT: Dizziness, LLT: Dizziness - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Oct 2020 16:14:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Oct 2020 16:14:08
Data point term sent to Coder	System	21 Oct 2020 16:08:41
User entered 'Dizziness'	Erika Faust (b) (4) (b) (4)	21 Oct 2020 16:08:13

US3542053
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 08:13:30
Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:41
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Oct 2020 18:32:30
User entered 'No (N)'	Erika Faust (b) (4) (b) (4)	21 Oct 2020 16:08:13

US3542053
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 08:13:30
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:41
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Oct 2020 18:32:30
User entered 'No (N)'	Erika Faust (b) (4) (b) (4)	21 Oct 2020 16:08:13

US3542053
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 08:13:30
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:41
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Oct 2020 18:32:30
User entered 'No (N)'	Erika Faust (b) (4) (b) (4)	21 Oct 2020 16:08:13

US3542053
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 08:13:30
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:41
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Oct 2020 18:32:30
User entered '20 Oct 2020'	Erika Faust (b) (4) (b) (4)	21 Oct 2020 16:08:13

US3542053
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 08:13:30
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:41
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Oct 2020 18:32:30
User entered empty.	Erika Faust (b) (4) (b) (4)	21 Oct 2020 16:08:13

US3542053
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 08:13:30
AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:41
User entered empty.	System	21 Oct 2020 16:08:13

US3542053
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 08:13:30
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:41
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Oct 2020 18:32:30
User entered 'No (N)'	Erika Faust (b) (4) (b) (4)	21 Oct 2020 16:08:13

US3542053
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 08:13:30
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:41
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Oct 2020 18:32:30
User entered '20 Oct 2020'	Erika Faust (b) (4) (b) (4)	21 Oct 2020 16:08:13

US3542053
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 08:13:30
End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:41
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Oct 2020 18:32:30
User entered empty.	Erika Faust (b) (4) (b) (4)	21 Oct 2020 16:08:13

US3542053
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 08:13:30
AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:41
User entered empty.	System	21 Oct 2020 16:08:13

US3542053
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 08:13:30
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:41
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Oct 2020 18:32:30
User entered 'Grade 1/Mild (Grade 1/Mild)'	Erika Faust (b) (4) (b) (4)	21 Oct 2020 16:08:13

US3542053
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 08:13:30
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:41
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Oct 2020 18:32:30
User entered 'No (N)'	Erika Faust (b) (4) (b) (4)	21 Oct 2020 16:08:13

US3542053
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 08:13:30
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:41
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Oct 2020 18:32:30
User entered '0'	Erika Faust (b) (4) (b) (4)	21 Oct 2020 16:08:13

US3542053
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 08:13:30
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:41
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Oct 2020 18:32:30
User entered '0'	Erika Faust (b) (4) (b) (4)	21 Oct 2020 16:08:13

US3542053
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 08:13:30
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:41
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Oct 2020 18:32:30
User entered '0'	Erika Faust (b) (4) (b) (4)	21 Oct 2020 16:08:13

US3542053
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 08:13:30
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:41
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Oct 2020 18:32:30
User entered empty.	Erika Faust (b) (4) (b) (4)	21 Oct 2020 16:08:13

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US3542053
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 08:13:30
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:41
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Oct 2020 18:32:30
User entered empty.	Erika Faust (b) (4) (b) (4)	21 Oct 2020 16:08:13

US3542053
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 08:13:30
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:41
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Oct 2020 18:32:30
User entered empty.	Erika Faust (b) (4) (b) (4)	21 Oct 2020 16:08:13

US3542053
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 08:13:30
Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:41
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Oct 2020 18:32:30
User entered empty.	Erika Faust (b) (4) (b) (4)	21 Oct 2020 16:08:13

US3542053
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 08:13:30
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:41
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Oct 2020 18:32:30
User entered '0'	Erika Faust (b) (4) (b) (4)	21 Oct 2020 16:08:13

US3542053
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 08:13:30
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:41
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Oct 2020 18:32:30
User entered '0'	Erika Faust (b) (4) (b) (4)	21 Oct 2020 16:08:13

US3542053
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 08:13:30
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:41
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Oct 2020 18:32:30
User entered '0'	Erika Faust (b) (4) (b) (4)	21 Oct 2020 16:08:13

US3542053
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 08:13:30
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:41
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Oct 2020 18:32:30
User entered 'Not Related (NOT RELATED)'	Erika Faust (b) (4) (b) (4)	21 Oct 2020 16:08:13

FDA-CBER-2022-1614-2661436

US3542053
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 08:13:30
Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:41
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Oct 2020 18:32:30
User entered 'Not Related (NOT RELATED)'	Erika Faust (b) (4) (b) (4)	21 Oct 2020 16:08:13

US3542053
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 08:13:30
Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:41
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4)	21 Oct 2020 18:32:30
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Erika Faust (b) (4) (b) (4)	21 Oct 2020 16:08:13

FDA-CBER-2022-1614-2661438

US3542053
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 08:13:30
None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:41
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Oct 2020 18:32:30
User entered '1'	Erika Faust (b) (4) (b) (4)	21 Oct 2020 16:08:13

US3542053
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 08:13:30
Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:41
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Oct 2020 18:32:30
User entered '0'	Erika Faust (b) (4) (b) (4)	21 Oct 2020 16:08:13

FDA-CBER-2022-1614-2661440

US3542053
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 08:13:30
Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:41
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Oct 2020 18:32:30
User entered '0'	Erika Faust (b) (4) (b) (4)	21 Oct 2020 16:08:13

US3542053
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 08:13:30
Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:41
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Oct 2020 18:32:30
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Erika Faust (b) (4) (b) (4)	21 Oct 2020 16:08:13

FDA-CBER-2022-1614-2661442

US3542053
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 08:13:30
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:41
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Oct 2020 18:32:30
User entered empty.	Erika Faust (b) (4) (b) (4)	21 Oct 2020 16:08:13

US3542053
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 08:13:30
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:41
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Oct 2020 18:32:30
User entered empty.	Erika Faust (b) (4) (b) (4)	21 Oct 2020 16:08:13

US3542053
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 08:13:30
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:41
User entered '0'	System	21 Oct 2020 16:08:13

FDA-CBER-2022-1614-2661445

US3542053
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 08:13:30
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:41
User entered '0'	System	21 Oct 2020 16:08:13

US3542053
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 08:13:30
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:41

FDA-CBER-2022-1614-2661447

US3542053
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 08:13:30
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:47

FDA-CBER-2022-1614-2661448

US3542053
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 08:13:30
Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:47
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	13 Jan 2021 03:41:29
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)	08 Jan 2021 18:34:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Jan 2021 18:34:42
Data point term sent to Coder	System	08 Jan 2021 18:33:37
User entered 'Atrial Fibrillation'	Erika Faust (b) (4) (b) (4)	08 Jan 2021 18:33:06

US3542053
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 08:13:30
Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:47
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	13 Jan 2021 03:41:29
User entered 'Yes (Y)'	Erika Faust (b) (4) (b) (4)	08 Jan 2021 18:33:06

US3542053
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 08:13:30
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:47
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	13 Jan 2021 03:41:29
User entered 'No (N)'	Erika Faust (b) (4) (b) (4)	08 Jan 2021 18:33:06

FDA-CBER-2022-1614-2661451

US3542053
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 08:13:30
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:47
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	13 Jan 2021 03:41:29
User entered 'No (N)'	Erika Faust (b) (4) (b) (4)	08 Jan 2021 18:33:06

FDA-CBER-2022-1614-2661452

US3542053
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 08:13:30
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:47
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	13 Jan 2021 03:41:29
User entered '15 Dec 2020'	Erika Faust (b) (4) (b) (4)	08 Jan 2021 18:33:06

FDA-CBER-2022-1614-2661453

US3542053
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 08:13:30
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:47
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	13 Jan 2021 03:41:29
User entered empty.	Erika Faust (b) (4) (b) (4)	08 Jan 2021 18:33:06

US3542053
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 08:13:30
AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:47
User entered empty.	System	08 Jan 2021 18:33:06

US3542053
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 08:13:30
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:47
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	13 Jan 2021 03:41:29
User entered 'No (N)'	Erika Faust (b) (4) (b) (4)	08 Jan 2021 18:33:06

FDA-CBER-2022-1614-2661456

US3542053
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 08:13:30
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:47
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	13 Jan 2021 03:41:29
User entered '23 Dec 2020'	Erika Faust (b) (4) (b) (4)	08 Jan 2021 18:33:06

FDA-CBER-2022-1614-2661457

US3542053
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 08:13:30
End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:47
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	13 Jan 2021 03:41:29
User entered empty.	Erika Faust (b) (4) (b) (4)	08 Jan 2021 18:33:06

US3542053
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 08:13:30
AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:47
User entered empty.	System	08 Jan 2021 18:33:06

FDA-CBER-2022-1614-2661459

US3542053
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 08:13:30
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:47
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:29
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Erika Faust (b) (4) (b) (4)	08 Jan 2021 18:33:06

FDA-CBER-2022-1614-2661460

US3542053
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 08:13:30
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:47
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	13 Jan 2021 03:41:29
User entered 'No (N)'	Erika Faust (b) (4) (b) (4)	08 Jan 2021 18:33:06

FDA-CBER-2022-1614-2661461

US3542053
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 08:13:30
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:47
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	13 Jan 2021 03:41:29
User entered '0'	Erika Faust (b) (4) (b) (4)	08 Jan 2021 18:33:06

FDA-CBER-2022-1614-2661462

US3542053
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 08:13:30
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:47
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	13 Jan 2021 03:41:29
User entered '0'	Erika Faust (b) (4) (b) (4)	08 Jan 2021 18:33:06

US3542053
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 08:13:30
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:47
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	13 Jan 2021 03:41:29
User entered '0'	Erika Faust (b) (4) (b) (4)	08 Jan 2021 18:33:06

US3542053
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 08:13:30
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:47
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	13 Jan 2021 03:41:29
User entered empty.	Erika Faust (b) (4) (b) (4)	08 Jan 2021 18:33:06

FDA-CBER-2022-1614-2661465

US3542053
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 08:13:30
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:47
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	13 Jan 2021 03:41:29
User entered empty.	Erika Faust (b) (4) (b) (4)	08 Jan 2021 18:33:06

US3542053
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 08:13:30
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:47
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	13 Jan 2021 03:41:29
User entered empty.	Erika Faust (b) (4) (b) (4)	08 Jan 2021 18:33:06

FDA-CBER-2022-1614-2661467

US3542053
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 08:13:30
Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:47
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	13 Jan 2021 03:41:29
User entered empty.	Erika Faust (b) (4) (b) (4)	08 Jan 2021 18:33:06

US3542053
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 08:13:30
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:47
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	13 Jan 2021 03:41:29
User entered '0'	Erika Faust (b) (4) (b) (4)	08 Jan 2021 18:33:06

FDA-CBER-2022-1614-2661469

US3542053
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 08:13:30
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:47
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	13 Jan 2021 03:41:29
User entered '0'	Erika Faust (b) (4) (b) (4)	08 Jan 2021 18:33:06

US3542053
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 08:13:30
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:47
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	13 Jan 2021 03:41:29
User entered '0'	Erika Faust (b) (4) (b) (4)	08 Jan 2021 18:33:06

FDA-CBER-2022-1614-2661471

US3542053
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 08:13:30
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:47
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	13 Jan 2021 03:41:29
User entered 'Not Related (NOT RELATED)'	Erika Faust (b) (4) (b) (4)	08 Jan 2021 18:33:06

US3542053
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 08:13:30
Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:47
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	13 Jan 2021 03:41:29
User entered 'Not Related (NOT RELATED)'	Erika Faust (b) (4) (b) (4)	08 Jan 2021 18:33:06

FDA-CBER-2022-1614-2661473

US3542053
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 08:13:30
Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:47
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4)	13 Jan 2021 03:41:29
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Erika Faust (b) (4) (b) (4)	08 Jan 2021 18:33:06

FDA-CBER-2022-1614-2661474

US3542053
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 08:13:30
None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:47
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	13 Jan 2021 03:41:29
User entered '0'	Erika Faust (b) (4) (b) (4)	08 Jan 2021 18:33:06

US3542053
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 08:13:30
Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:47
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	13 Jan 2021 03:41:29
User entered '1'	Erika Faust (b) (4) (b) (4)	08 Jan 2021 18:33:06

US3542053
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 08:13:30
Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:47
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	13 Jan 2021 03:41:29
User entered '1'	Erika Faust (b) (4) (b) (4)	08 Jan 2021 18:33:06

FDA-CBER-2022-1614-2661477

US3542053
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 08:13:30
Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:47
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	13 Jan 2021 03:41:29
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Erika Faust (b) (4) (b) (4)	08 Jan 2021 18:33:06

FDA-CBER-2022-1614-2661478

US3542053
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 08:13:30
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:47
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	13 Jan 2021 03:41:29
User entered empty.	Erika Faust (b) (4) (b) (4)	08 Jan 2021 18:33:06

US3542053
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 08:13:30
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:47
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	13 Jan 2021 03:41:29
User entered empty.	Erika Faust (b) (4) (b) (4)	08 Jan 2021 18:33:06

FDA-CBER-2022-1614-2661480

US3542053
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 08:13:30
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:47
User entered '0'	System	08 Jan 2021 18:33:06

US3542053
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 08:13:30
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:47
User entered '1'	System	08 Jan 2021 18:33:06

US3542053
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 08:13:30
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:47

FDA-CBER-2022-1614-2661483

US3542053
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 08:13:30
AEID

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:14:38
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered 'USA-US084-2021-mRNA-1273-P301000004'	System	11 Feb 2021 19:22:51
User entered 'New'	(b) (4), (b) (6)	11 Feb 2021 19:22:51

FDA-CBER-2022-1614-2661484

US3542053
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 08:13:30
Adverse event

Audit	User	Time (GMT)
User closed query 'PV Query: Please assess whether acute heart failure meets criteria for serious event.' (Site from Safety).	(b) (4), (b) (6)	22 Feb 2021 18:14:27
Query 'PV Query: Please assess whether acute heart failure meets criteria for serious event.' answered with 'Acute heart failure is a manifestation/complication of atrial flutter and should not be considered as a separate event.' (Site from Safety).	David Diemert (b) (4) (b) (4)	19 Feb 2021 22:35:04
User opened query 'PV Query: Please assess whether acute heart failure meets criteria for serious event.' (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 05:13:06
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial flutter, LLT: Atrial flutter - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Feb 2021 22:27:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Feb 2021 22:27:50
Data point term sent to Coder	System	10 Feb 2021 22:26:30
User entered 'Atrial Flutter'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:25:45

US3542053
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 08:13:30
Was this a medically-attended AE?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Feb 2021 22:26:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Feb 2021 22:26:03
User entered 'Yes (Y)' reason for change: Data Entry Error	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:26:03
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Feb 2021 22:25:45
User entered empty.	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:25:45

FDA-CBER-2022-1614-2661486

US3542053
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 08:13:30
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered 'No (N)'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:25:45

US3542053
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 08:13:30
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered 'No (N)'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:25:45

US3542053
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 08:13:30
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered '04 Feb 2021' reason for change: Data Entry Error	Erika Faust (b) (4) (b) (4)	11 Feb 2021 16:52:25
User entered '4 Feb 2021'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:25:45

US3542053
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 08:13:30
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered empty.	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:25:45

US3542053
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 08:13:30
AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	10 Feb 2021 22:25:45

US3542053
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 08:13:30
Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered 'No (N)'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:25:45

US3542053
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 08:13:30
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered '08 Feb 2021' reason for change: Data Entry Error	Erika Faust (b) (4) (b) (4)	11 Feb 2021 16:52:25
User entered '8 Feb 2021'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:25:45

US3542053
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 08:13:30
End time *(00:00-23:59)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered empty.	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:25:45

US3542053
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 08:13:30
AE End Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	10 Feb 2021 22:25:45

US3542053
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 08:13:30
Severity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:00:52
User entered 'Grade 3/Severe (Grade 3/Severe)'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:25:45

US3542053
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 08:13:30
Is the adverse event serious?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered 'Yes (Y)'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:25:45

FDA-CBER-2022-1614-2661497

US3542053
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 08:13:30
Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:00:52
User entered '0'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:25:45

FDA-CBER-2022-1614-2661498

US3542053
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 08:13:30
Life threatening

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:00:52
User entered '0'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:25:45

FDA-CBER-2022-1614-2661499

US3542053
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 08:13:30
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:00:52
User entered '1'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:25:45

US3542053
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 08:13:30
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered '04 Feb 2021' reason for change: Data Entry Error	Erika Faust (b) (4) (b) (4)	11 Feb 2021 16:52:25
User entered '4 Feb 2021'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:25:45

US3542053
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 08:13:30
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered '08 Feb 2021' reason for change: Data Entry Error	Erika Faust (b) (4) (b) (4)	11 Feb 2021 16:52:25
User entered '8 Feb 2021'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:25:45

US3542053
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 08:13:30
Admitted to ICU?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered 'No (N)'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:25:45

US3542053
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 08:13:30
Number of Days in ICU

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered empty.	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:25:45

US3542053
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 08:13:30
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered '0'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:25:45

US3542053
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 08:13:30
Congenital anomaly or birth defect

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered '0'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:25:45

US3542053
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 08:13:30
Other medically important event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered '0'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:25:45

US3542053
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 08:13:30
Relationship to investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered 'Not Related (NOT RELATED)'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:25:45

US3542053
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 08:13:30
Relationship to Study Procedure

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:00:52
User entered 'Not Related (NOT RELATED)'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:25:45

US3542053
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 08:13:30
Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:00:52
User entered 'Dose Delayed (DOSE DELAYED)'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:25:45

US3542053
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 08:13:30
None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered '0'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:25:45

US3542053
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 08:13:30
Concomitant Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:00:52
User entered '1'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:25:45

US3542053
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 08:13:30
Concomitant Procedure

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:00:52
User entered '1'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:25:45

US3542053
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 08:13:30
Outcome

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:25:45

US3542053
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 08:13:30
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered empty.	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:25:45

US3542053
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 08:13:30
Narrative

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:54:37
User signature succeeded.	David Diemert (b) (4) (b) (4)	12 Mar 2021 22:39:58
User closed query 'Per DM CLR: Narrative = ELEVATED BNP. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 08:02:00
User closed query 'Per DM CLR: Narrative = EVIDENCE OF PULMONARY EDEMA. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 06:42:37
User closed query 'Per DM CLR: Narrative = CXR. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 06:41:04
Query 'Per DM CLR: Narrative = ELEVATED BNP. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'this is a blood test and does not need to be added to the con procedure log' (Site from DM).	Elissa Malkin (b) (4) (b) (4)	10 Mar 2021 19:11:53
Query 'Per DM CLR: Narrative = EVIDENCE OF PULMONARY EDEMA. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate. ' answered with 'this is not a separate AE- acute heart failure is listed as an AE which suffices' (Site from DM).	Elissa Malkin (b) (4) (b) (4)	10 Mar 2021 19:10:02
Query 'Per DM CLR: Narrative = CXR. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'a chest x-ray is not considered a procedure - this is a test and not a procedure' (Site from DM).	Elissa Malkin (b) (4) (b) (4)	10 Mar 2021 19:07:34

US3542053
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 08:13:30
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. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	09 Mar 2021 16:09:21
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	09 Mar 2021 16:09:13
User opened query 'Per DM CLR: Narrative = CXR. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 05:23:30
User opened query 'Per DM CLR: Narrative = EVIDENCE OF PULMONARY EDEMA. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 05:23:23
User opened query 'Per DM CLR: Narrative = ELEVATED BNP. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 05:23:16
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 'records sent today 08MAR2021' (Site from Safety).	Elissa Malkin (b) (4) (b) (4)	08 Mar 2021 20:53:02

US3542053
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 08:13:30
Narrative

Audit	User	Time (GMT)
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' answered with 'records sent today 08MAR2021' (Site from Safety).	Elissa Malkin (b) (4) (b) (4)	08 Mar 2021 20:52:49
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)	26 Feb 2021 05:16:56
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	22 Feb 2021 18:14:35
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)	22 Feb 2021 18:14:32
DataPoint Un-verified.	David Diemert (b) (4) (b) (4)	19 Feb 2021 22:51:38
Signature has been broken.	David Diemert (b) (4) (b) (4)	19 Feb 2021 22:51:38

US3542053
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 08:13:30
Narrative

Audit	User	Time (GMT)
User entered 'PT PRESENTED TO ED ON 4-FEB-2021 WITH TACHYCARDIA (160S), HEADACHE, DYSPNEA AND PALPITATIONS. PARTICIPANT WAS FOUND TO BE IN ATRIAL FLUTTER AND POSSIBLE ACUTE HEART FAILURE AND WAS ADMITTED FOR FURTHER MANAGEMENT AND OBSERVATION. PARTICIPANT HAD ELEVATED BNP AND EVIDENCE OF PULMONARY EDEMA ON CXR. Admission COVID-19 PCR test on 04FEB2021 was negative. PARTICIPANT RECEIVED IV METOPROLOL WITH GOOD RESPONSE. SHE WAS RESTARTED ON PO METOPROLOL AND TRANSITIONED TO SOTALOL. SHE WAS GIVEN ONE DOSE OF IV LASIX WITH GOOD RESPONSE. PARTICIPANT UNDERWENT TTE ON 5-FEB-21 WHICH SHOWED EF 55-60%. TTE WAS REPEATED ON 7-FEB-21 AND SHOWED EF 50-55%. PARTICIPANT UNDERWENT CARDIOVERSION ON 8-FEB-21 AND WAS DISCHARGED LATER THAT DAY. PARTICIPANT HAS BEEN FEELING WELL OVERALL AND HAS REMAINED ASYMPTOMATIC SINCE 8-FEB-2021.' reason for change: New Information	David Diemert (b) (4) (b) (4)	19 Feb 2021 22:51:38
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 'COVID-19 PCR testing was done on admission to hospital, on 04FEB2021 and was negative.' (Site from Safety).	David Diemert (b) (4) (b) (4)	19 Feb 2021 22:50:57

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Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 08:13:30
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 'Acute heart failure is a direct consequence/manifestation of atrial flutter. This should NOT be considered as a separate event.' (Site from Safety).	David Diemert (b) (4) (b) (4)	19 Feb 2021 20:58:04
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 05:14:02
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.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 05:13:50
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)	19 Feb 2021 05:13:28
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52

US3542053
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 08:13:30
Narrative

Audit	User	Time (GMT)
User entered 'Pt presented to ED on 4-FEB-2021 with tachycardia (160s), headache, dyspnea and palpitations. Participant was found to be in atrial flutter and possible acute heart failure and was admitted for further management and observation. Participant had elevated BNP and evidence of pulmonary edema on CXR. Participant received IV metoprolol with good response. She was restarted on PO metoprolol and transitioned to sotalol. She was given one dose of IV lasix with good response. Participant underwent TTE on 5-FEB-21 which showed EF 55-60%. TTE was repeated on 7-FEB-21 and showed EF 50-55%. Participant underwent cardioversion on 8-FEB-21 and was discharged later that day. Participant has been feeling well overall and has remained asymptomatic since 8-FEB-2021.'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:25:45

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US3542053
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 08:13:30
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '1'	System	10 Feb 2021 22:25:45

US3542053
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 08:13:30
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	10 Feb 2021 22:26:03

US3542053
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 08:13:30
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	10 Feb 2021 22:25:45

US3542053
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 08:13:30
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:50

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US3542053
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 08:13:30
Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:50
User closed query 'Per MM: Please confirm this AE does not meet the definition of an SAE.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 10:33:55
Query 'Per MM: Please confirm this AE does not meet the definition of an SAE.' answered with 'It did not. The participant's hospitalization was due to atrial flutter. There was some secondary heart failure due to this but the primary reason for admission was atrial flutter.' (Site from DM).	David Diemert (b) (4) (b) (4)	18 Mar 2021 18:08:26
User opened query 'Per MM: Please confirm this AE does not meet the definition of an SAE.' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 15:55:11
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User coded data point as SOC: Cardiac disorders, HLGT: Heart failures, HLT: Heart failures NEC, PT: Cardiac failure acute, LLT: Acute heart failure - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Feb 2021 22:30:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Feb 2021 22:30:46
Data point term sent to Coder	System	10 Feb 2021 22:29:37
User entered 'Acute heart failure'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:28:40

US3542053
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 08:13:30
Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:50
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:00:52
User entered 'Yes (Y)'	(b) (4) Caroline Thoreson (b) (4)	10 Feb 2021 22:28:40

US3542053
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 08:13:30
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:50
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:00:52
User entered 'No (N)'	(b) (4) Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:28:40

US3542053
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 08:13:30
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:50
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered 'No (N)'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:28:40

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US3542053
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 08:13:30
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:50
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered '04 Feb 2021' reason for change: Data Entry Error	Erika Faust (b) (4) (b) (4)	11 Feb 2021 16:52:54
User entered '4 Feb 2021'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:28:40

US3542053
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 08:13:30
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:50
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered empty.	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:28:40

US3542053
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 08:13:30
AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:50
User entered empty.	System	10 Feb 2021 22:28:40

US3542053
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 08:13:30
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:50
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:00:52
User entered 'No (N)'	(b) (4) Caroline Thoreson (b) (4)	10 Feb 2021 22:28:40

US3542053
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 08:13:30
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:50
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered '08 Feb 2021' reason for change: Data Entry Error	Erika Faust (b) (4) (b) (4)	11 Feb 2021 16:52:54
User entered '8 Feb 2021'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:28:40

US3542053
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 08:13:30
End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:50
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:00:52
User entered empty.	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:28:40

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US3542053
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 08:13:30
AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:50
User entered empty.	System	10 Feb 2021 22:28:40

US3542053
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 08:13:30
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:50
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:00:52
User entered 'Grade 3/Severe (Grade 3/Severe)'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:28:40

US3542053
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 08:13:30
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:50
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered 'No (N)'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:28:40

US3542053
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 08:13:30
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:50
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:00:52
User entered '0'	(b) (4) Caroline Thoreson (b) (4)	10 Feb 2021 22:28:40

US3542053
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 08:13:30
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:50
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:00:52
User entered '0'	(b) (4) Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:28:40

US3542053
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 08:13:30
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:50
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:00:52
User entered '0'	(b) (4) Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:28:40

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US3542053
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 08:13:30
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:50
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered empty.	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:28:40

US3542053
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 08:13:30
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:50
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:00:52
User entered empty.	(b) (4) Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:28:40

US3542053
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 08:13:30
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:50
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:00:52
User entered empty.	(b) (4) Caroline Thoreson (b) (4)	10 Feb 2021 22:28:40

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US3542053
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 08:13:30
Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:50
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:00:52
User entered empty.	(b) (4) Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:28:40

US3542053
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 08:13:30
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:50
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:00:52
User entered '0'	(b) (4) Caroline Thoreson (b) (4)	10 Feb 2021 22:28:40

US3542053
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 08:13:30
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:50
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:00:52
User entered '0'	(b) (4) Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:28:40

US3542053
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 08:13:30
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:50
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:00:52
User entered '0'	(b) (4) Caroline Thoreson (b) (4)	10 Feb 2021 22:28:40

US3542053
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 08:13:30
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:50
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:00:52
User entered 'Not Related (NOT RELATED)'	(b) (4) Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:28:40

US3542053
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 08:13:30
Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:50
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:00:52
User entered 'Not Related (NOT RELATED)'	(b) (4) Caroline Thoreson (b) (4)	10 Feb 2021 22:28:40

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US3542053
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 08:13:30
Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:50
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:00:52
User entered 'None (NONE)'	(b) (4) Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:28:40

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US3542053
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 08:13:30
None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:50
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:00:52
User entered '0'	(b) (4) Caroline Thoreson (b) (4)	10 Feb 2021 22:28:40

US3542053
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 08:13:30
Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:50
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:00:52
User entered '1'	(b) (4) Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:28:40

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US3542053
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 08:13:30
Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:50
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:00:52
User entered '0'	(b) (4) Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:28:40

US3542053
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 08:13:30
Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:50
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:00:52
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:28:40

US3542053
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 08:13:30
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:50
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:00:52
User entered empty.	(b) (4) Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:28:40

US3542053
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 08:13:30
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:50
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:12:59
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:00:52
User entered empty.	(b) (4) Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:28:40

US3542053
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 08:13:30
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:50
User entered '0'	System	10 Feb 2021 22:28:40

US3542053
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 08:13:30
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:50
User entered '1'	System	10 Feb 2021 22:28:40

US3542053
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 08:13:30
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:10:50

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US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination Summary
Generated On: 10 Jun 2021 08:13:30
Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:47:56
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:09:03
User signature succeeded.	David Diemert (b) (4)	27 Aug 2020 15:41:44
User entered 'Yes (Y)'	(b) (4) Madhu Balachandran (b) (4)	26 Aug 2020 17:12:11

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 08:13:30
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:50
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: VITAMIN K ANTAGONISTS, PRODUCT: WARFARIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Aug 2020 11:09:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Aug 2020 11:09:34
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:41:44
Data point term sent to Coder	System	26 Aug 2020 17:14:07
User entered 'Warfarin'	Madhu Balachandran (b) (4)	26 Aug 2020 17:13:23

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 08:13:30
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:50
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:41:44
User entered 'No (N)'	Madhu Balachandran (b) (4)	26 Aug 2020 17:13:23

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 08:13:30
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:50
User closed query 'Per DM CLR: Please note that there is no ConProc that matches this Con Med indication during this time frame. Please review Con Med use and add the medical procedure in the ConProc eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 10:52:04
Query 'Per DM CLR: Please note that there is no ConProc that matches this Con Med indication during this time frame. Please review Con Med use and add the medical procedure in the ConProc eCRF as appropriate. ' answered with 'Mitral valve replacement is past medical history in 1984' (Site from DM).	Elissa Malkin (b) (4) (b) (4)	15 Mar 2021 17:28:09
User opened query 'Per DM CLR: Please note that there is no ConProc that matches this Con Med indication during this time frame. Please review Con Med use and add the medical procedure in the ConProc eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 07:36:10
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:41:44
User entered 'Mitral Valve Replacement'	Madhu Balachandran (b) (4)	26 Aug 2020 17:13:23

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 08:13:30
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:50
User signature succeeded.	David Diemert (b) (4) (b) (4)	15 Mar 2021 20:17:40
Signature has been broken.	Elissa Malkin (b) (4) (b) (4)	15 Mar 2021 17:33:54
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:41:44
User entered '6'	Madhu Balachandran (b) (4)	26 Aug 2020 17:13:23

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 08:13:30
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:50
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:41:44
User entered 'mg (mg)'	Madhu Balachandran (b) (4)	26 Aug 2020 17:13:23

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 08:13:30
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:50
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:41:44
User entered empty.	Madhu Balachandran (b) (4)	26 Aug 2020 17:13:23

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 08:13:30
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:50
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:41:44
User entered 'other (OTHER)'	Madhu Balachandran (b) (4)	26 Aug 2020 17:13:23

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 08:13:30
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:50
User signature succeeded.	David Diemert (b) (4) (b) (4)	15 Mar 2021 20:17:40
Signature has been broken.	Elissa Malkin (b) (4) (b) (4)	15 Mar 2021 17:34:37
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:41:44
User entered 'once Monday through Saturday'	Madhu Balachandran (b) (4)	26 Aug 2020 17:13:23

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 08:13:30
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:50
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:41:44
User entered 'Oral (ORAL)'	Madhu Balachandran (b) (4)	26 Aug 2020 17:13:23

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 08:13:30
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:50
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:41:44
User entered empty.	Madhu Balachandran (b) (4)	26 Aug 2020 17:13:23

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 08:13:30
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:50
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:41:44
User entered 'UN UNK 1984'	Madhu Balachandran (b) (4)	26 Aug 2020 17:13:23

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 08:13:30
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:50
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:41:44
User entered '0'	Madhu Balachandran (b) (4)	26 Aug 2020 17:13:23

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 08:13:30
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:50
User signature succeeded.	David Diemert (b) (4) (b) (4)	25 Feb 2021 20:43:24
Signature has been broken.	Erika Faust (b) (4) (b) (4)	24 Feb 2021 16:47:47
User entered 'No (N)' reason for change: New Information	Erika Faust (b) (4) (b) (4)	24 Feb 2021 16:47:47
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:41:44
User entered 'Yes (Y)'	Madhu Balachandran (b) (4)	26 Aug 2020 17:13:23

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 08:13:30
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:50
User signature succeeded.	David Diemert (b) (4) (b) (4)	25 Feb 2021 20:43:24
Signature has been broken.	Erika Faust (b) (4) (b) (4)	24 Feb 2021 16:47:47
User entered '05 Feb 2021' reason for change: New Information	Erika Faust (b) (4) (b) (4)	24 Feb 2021 16:47:47
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:41:44
User entered empty.	Madhu Balachandran (b) (4)	26 Aug 2020 17:13:23

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 08:13:30
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:50
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:41:44
User entered 'No (N)'	Madhu Balachandran (b) (4)	26 Aug 2020 17:13:23

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 08:13:30
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:50
User entered empty.	System	26 Aug 2020 17:13:23

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 08:13:30
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:50
User entered empty.	System	26 Aug 2020 17:13:23

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 08:13:30
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:50
User entered empty.	System	26 Aug 2020 17:13:23

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 08:13:30
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:56
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: VITAMIN K ANTAGONISTS, PRODUCT: WARFARIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Aug 2020 11:09:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Aug 2020 11:09:34
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:41:44
Data point term sent to Coder	System	26 Aug 2020 17:15:08
User entered 'Warfarin'	Madhu Balachandran (b) (4)	26 Aug 2020 17:14:14

FDA-CBER-2022-1614-2661580

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 08:13:30
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:56
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:41:44
User entered 'No (N)'	Madhu Balachandran (b) (4)	26 Aug 2020 17:14:14

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 08:13:30
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:56
User closed query 'Per DM CLR: Please note that there is no ConProc that matches this Con Med indication during this time frame. Please review Con Med use and add the medical procedure in the ConProc eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 10:52:11
Query 'Per DM CLR: Please note that there is no ConProc that matches this Con Med indication during this time frame. Please review Con Med use and add the medical procedure in the ConProc eCRF as appropriate. ' answered with 'Mitral valve replacement is past medical history ' (Site from DM).	Elissa Malkin (b) (4) (b) (4)	15 Mar 2021 17:28:34
User opened query 'Per DM CLR: Please note that there is no ConProc that matches this Con Med indication during this time frame. Please review Con Med use and add the medical procedure in the ConProc eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 07:36:45
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:41:44
User entered 'Mitral Valve Replacement'	Madhu Balachandran (b) (4)	26 Aug 2020 17:14:14

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 08:13:30
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:56
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 10:52:18
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'This is the dosage taken and warfarin is routinely adjusted to a patient's specific needs' (Site from DM).	Elissa Malkin (b) (4) (b) (4)	15 Mar 2021 17:29:39
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 07:36:53
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:41:44
User entered '7'	Madhu Balachandran (b) (4)	26 Aug 2020 17:14:14

FDA-CBER-2022-1614-2661583

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 08:13:30
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:56
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:41:44
User entered 'mg (mg)'	Madhu Balachandran (b) (4)	26 Aug 2020 17:14:14

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 08:13:30
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:56
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:41:44
User entered empty.	Madhu Balachandran (b) (4)	26 Aug 2020 17:14:14

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 08:13:30
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:56
User closed query 'Per CDM: Frequency is updated as other however "Every week" is already available as pre-coded option at this field. Please consider to update frequency as "Every week" and remove data from If frequency is Other, specify. Thank you.' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 08:31:27
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 15:30:59
Query 'Per CDM: Frequency is updated as other however "Every week" is already available as pre-coded option at this field. Please consider to update frequency as "Every week" and remove data from If frequency is Other, specify. Thank you.' answered with 'Frequency updated to every week per query resolution' (Site from DM).	Hannah Yellin (b) (4) (b) (4)	04 Sep 2020 14:45:30
Signature has been broken.	Hannah Yellin (b) (4) (b) (4)	04 Sep 2020 14:45:21
User entered 'every week (QS)' reason for change: Per Query Resolution	Hannah Yellin (b) (4) (b) (4)	04 Sep 2020 14:45:21
User opened query 'Per CDM: Frequency is updated as other however "Every week" is already available as pre-coded option at this field. Please consider to update frequency as "Every week" and remove data from If frequency is Other, specify. Thank you.' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 06:34:52
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:41:44
User entered 'other (OTHER)'	Madhu Balachandran (b) (4)	26 Aug 2020 17:14:14

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 08:13:30
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:56
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 15:30:59
Signature has been broken.	Hannah Yellin (b) (4) (b) (4)	04 Sep 2020 14:45:21
User entered empty; reason for change Per Query Resolution	Hannah Yellin (b) (4) (b) (4)	04 Sep 2020 14:45:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:41:44
User entered 'Once on Sunday'	Madhu Balachandran (b) (4)	26 Aug 2020 17:14:14

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 08:13:30
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:56
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:41:44
User entered 'Oral (ORAL)'	Madhu Balachandran (b) (4)	26 Aug 2020 17:14:14

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 08:13:30
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:56
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:41:44
User entered empty.	Madhu Balachandran (b) (4)	26 Aug 2020 17:14:14

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 08:13:30
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:56
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:41:44
User entered 'UN UNK 1984'	Madhu Balachandran (b) (4)	26 Aug 2020 17:14:14

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 08:13:30
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:56
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:41:44
User entered '0'	Madhu Balachandran (b) (4)	26 Aug 2020 17:14:14

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 08:13:30
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:56
User signature succeeded.	David Diemert (b) (4) (b) (4)	25 Feb 2021 20:43:24
Signature has been broken.	Erika Faust (b) (4) (b) (4)	24 Feb 2021 16:48:06
User entered 'No (N)' reason for change: New Information	Erika Faust (b) (4) (b) (4)	24 Feb 2021 16:48:06
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:41:44
User entered 'Yes (Y)'	Madhu Balachandran (b) (4)	26 Aug 2020 17:14:14

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 08:13:30
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:56
User signature succeeded.	David Diemert (b) (4) (b) (4)	25 Feb 2021 20:43:24
Signature has been broken.	Erika Faust (b) (4) (b) (4)	24 Feb 2021 16:48:06
User entered '04 Feb 2021' reason for change: New Information	Erika Faust (b) (4) (b) (4)	24 Feb 2021 16:48:06
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:41:44
User entered empty.	Madhu Balachandran (b) (4)	26 Aug 2020 17:14:14

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 08:13:30
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:56
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Aug 2020 15:41:44
User entered 'No (N)'	Madhu Balachandran (b) (4)	26 Aug 2020 17:14:14

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 08:13:30
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:56
User entered '1'	System	04 Sep 2020 14:45:21
User entered empty.	System	26 Aug 2020 17:14:14

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 08:13:30
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:56
User entered '1'	System	04 Sep 2020 14:45:21
User entered empty.	System	26 Aug 2020 17:14:14

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 08:13:30
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:30:56
User entered '803 (803)'	System	04 Sep 2020 14:45:21
User entered empty.	System	26 Aug 2020 17:14:14

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 08:13:30
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	23 Sep 2020 15:17:42
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: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 18:47:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 18:47:51
Data point term sent to Coder	System	22 Sep 2020 18:46:30
User entered 'Famotidine'	Madhu Balachandran (b) (4)	22 Sep 2020 18:45:32

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US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 08:13:30
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	23 Sep 2020 15:17:42
User entered 'No (N)'	Madhu Balachandran (b) (4)	22 Sep 2020 18:45:32

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 08:13:30
Indication

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	23 Sep 2020 15:17:42
User entered 'Gastritis'	Madhu Balachandran (b) (4)	22 Sep 2020 18:45:32

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 08:13:30
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	23 Sep 2020 15:17:42
User entered '20'	Madhu Balachandran (b) (4)	22 Sep 2020 18:45:32

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 08:13:30
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	23 Sep 2020 15:17:42
User entered 'mg (mg)'	Madhu Balachandran (b) (4)	22 Sep 2020 18:45:32

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 08:13:30
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	23 Sep 2020 15:17:42
User entered empty.	Madhu Balachandran (b) (4)	22 Sep 2020 18:45:32

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 08:13:30
Frequency

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	23 Sep 2020 15:17:42
User entered 'twice daily (BID)'	Madhu Balachandran (b) (4)	22 Sep 2020 18:45:32

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 08:13:30
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	23 Sep 2020 15:17:42
User entered empty.	Madhu Balachandran (b) (4)	22 Sep 2020 18:45:32

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 08:13:30
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	23 Sep 2020 15:17:42
User entered 'Oral (ORAL)'	Madhu Balachandran (b) (4)	22 Sep 2020 18:45:32

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 08:13:30
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	23 Sep 2020 15:17:42
User entered empty.	Madhu Balachandran (b) (4)	22 Sep 2020 18:45:32

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 08:13:30
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	23 Sep 2020 15:17:42
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	22 Sep 2020 18:46:06
User entered '13 Sep 2020' reason for change: Data Entry Error	Madhu Balachandran (b) (4)	22 Sep 2020 18:46:06
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	22 Sep 2020 18:45:32
User entered '13 Sep 20' (non-conformant).	Madhu Balachandran (b) (4)	22 Sep 2020 18:45:32

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 08:13:30
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	23 Sep 2020 15:17:42
User entered '0'	Madhu Balachandran (b) (4)	22 Sep 2020 18:45:32

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 08:13:30
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	23 Sep 2020 15:17:42
User entered 'Yes (Y)'	Madhu Balachandran (b) (4)	22 Sep 2020 18:45:32

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 08:13:30
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	23 Sep 2020 15:17:42
User entered empty.	Madhu Balachandran (b) (4)	22 Sep 2020 18:45:32

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 08:13:30
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	23 Sep 2020 15:17:42
User entered 'No (N)'	Madhu Balachandran (b) (4)	22 Sep 2020 18:45:32

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 08:13:30
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '2'	System	22 Sep 2020 18:45:32

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 08:13:30
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 18:45:32

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 08:13:30
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Sep 2020 18:45:32

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 08:13:30
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:27:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	23 Sep 2020 15:17:42
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: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 18:47:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 18:47:51
Data point term sent to Coder	System	22 Sep 2020 18:46:30
User entered 'Omeprazole'	Madhu Balachandran (b) (4)	22 Sep 2020 18:45:56

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US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 08:13:30
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:27:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	23 Sep 2020 15:17:42
User entered 'No (N)'	Madhu Balachandran (b) (4)	22 Sep 2020 18:45:56

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 08:13:30
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:27:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	23 Sep 2020 15:17:42
User entered 'Gastritis'	Madhu Balachandran (b) (4)	22 Sep 2020 18:45:56

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 08:13:30
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:27:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	23 Sep 2020 15:17:42
User entered '20'	Madhu Balachandran (b) (4)	22 Sep 2020 18:45:56

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 08:13:30
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:27:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	23 Sep 2020 15:17:42
User entered 'mg (mg)'	Madhu Balachandran (b) (4)	22 Sep 2020 18:45:56

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 08:13:30
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:27:21
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:17:42
User entered empty.	Madhu Balachandran (b) (4)	22 Sep 2020 18:45:56

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 08:13:30
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:27:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	23 Sep 2020 15:17:42
User entered 'once daily (QD)'	Madhu Balachandran (b) (4)	22 Sep 2020 18:45:56

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 08:13:30
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:27:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	23 Sep 2020 15:17:42
User entered empty.	Madhu Balachandran (b) (4)	22 Sep 2020 18:45:56

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 08:13:30
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:27:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	23 Sep 2020 15:17:42
User entered 'Oral (ORAL)'	Madhu Balachandran (b) (4)	22 Sep 2020 18:45:56

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 08:13:30
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:27:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	23 Sep 2020 15:17:42
User entered empty.	Madhu Balachandran (b) (4)	22 Sep 2020 18:45:56

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 08:13:30
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:27:21
User signature succeeded.	David Diemert (b) (4)	23 Sep 2020 15:17:42
User entered '13 Sep 2020'	Madhu Balachandran (b) (4)	22 Sep 2020 18:45:56

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 08:13:30
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:27:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	23 Sep 2020 15:17:42
User entered '0'	Madhu Balachandran (b) (4)	22 Sep 2020 18:45:56

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 08:13:30
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:27:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	18 Dec 2020 16:14:51
Signature has been broken.	Erika Faust (b) (4) (b) (4)	18 Dec 2020 16:09:12
User entered 'No (N)' reason for change: New Information	Erika Faust (b) (4) (b) (4)	18 Dec 2020 16:09:12
User signature succeeded.	David Diemert (b) (4) (b) (4)	23 Sep 2020 15:17:42
User entered 'Yes (Y)'	Madhu Balachandran (b) (4)	22 Sep 2020 18:45:56

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 08:13:30
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:27:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	18 Dec 2020 16:14:51
Signature has been broken.	Erika Faust (b) (4) (b) (4)	18 Dec 2020 16:09:12
User entered 'UN Oct 2020' reason for change: New Information	Erika Faust (b) (4) (b) (4)	18 Dec 2020 16:09:12
User signature succeeded.	David Diemert (b) (4) (b) (4)	23 Sep 2020 15:17:42
User entered empty.	Madhu Balachandran (b) (4)	22 Sep 2020 18:45:56

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US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 08:13:30
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:27:21
User signature succeeded.	David Diemert (b) (4) (b) (4)	23 Sep 2020 15:17:42
User entered 'No (N)'	Madhu Balachandran (b) (4)	22 Sep 2020 18:45:56

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 08:13:30
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:27:21
User entered '1'	System	22 Sep 2020 18:45:56

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 08:13:30
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:27:21
User entered '1'	System	22 Sep 2020 18:45:56

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US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 08:13:30
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:27:21
User entered '804 (804)'	System	22 Sep 2020 18:45:56

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 08:13:30
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:13
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: LIDOCAINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 06:11:11
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 06:11:11
User signature succeeded.	David Diemert (b) (4) (b) (4)	30 Sep 2020 22:38:17
Data point term sent to Coder	System	30 Sep 2020 18:34:27
User entered 'lidocaine 5% patch'	DeEnna Wedding (b) (4) (b) (4)	30 Sep 2020 18:34:10

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 08:13:30
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:13
User signature succeeded.	David Diemert (b) (4) (b) (4)	30 Sep 2020 22:38:17
User entered 'No (N)'	DeEnna Wedding (b) (4) (b) (4)	30 Sep 2020 18:34:10

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 08:13:30
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:13
User signature succeeded.	David Diemert (b) (4) (b) (4)	30 Sep 2020 22:38:17
User entered 'back pain, lower'	DeEnna Wedding (b) (4) (b) (4)	30 Sep 2020 18:34:10

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 08:13:30
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:13
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Nov 2020 04:10:23
User closed query 'Per DM CLR: Please note, 5 % pertains to drug concentration/strength. So please verify if the DOSE reflecting the single dose taken by the subject in # of applications (e.g., Dose=1, If dose unit is Other, specify = application) would be more appropriate recording. If so, update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 06:03:30
Query 'Per DM CLR: Please note, 5 % pertains to drug concentration/strength. So please verify if the DOSE reflecting the single dose taken by the subject in # of applications (e.g., Dose=1, If dose unit is Other, specify = application) would be more appropriate recording. If so, update eCRF as appropriate.' answered with 'updated' (Site from DM).	Elissa Malkin (b) (4) (b) (4)	17 Nov 2020 21:45:51
Signature has been broken.	Elissa Malkin (b) (4) (b) (4)	17 Nov 2020 21:45:16
User entered 'one' reason for change: Per Query Resolution	Elissa Malkin (b) (4) (b) (4)	17 Nov 2020 21:45:16
User opened query 'Per DM CLR: Please note, 5 % pertains to drug concentration/strength. So please verify if the DOSE reflecting the single dose taken by the subject in # of applications (e.g., Dose=1, If dose unit is Other, specify = application) would be more appropriate recording. If so, update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 09:35:05
User signature succeeded.	David Diemert (b) (4) (b) (4)	30 Sep 2020 22:38:17
User entered '5'	DeEnna Wedding (b) (4) (b) (4)	30 Sep 2020 18:34:10

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US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 08:13:30
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:13
User signature succeeded.	David Diemert (b) (4) (b) (4)	30 Sep 2020 22:38:17
User entered 'Other (OTHER)'	DeEnna Wedding (b) (4) (b) (4)	30 Sep 2020 18:34:10

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 08:13:30
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:13
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Nov 2020 04:10:23
Signature has been broken.	Elissa Malkin (b) (4) (b) (4)	17 Nov 2020 21:45:16
User entered 'application' reason for change: Per Query Resolution	Elissa Malkin (b) (4) (b) (4)	17 Nov 2020 21:45:16
User signature succeeded.	David Diemert (b) (4) (b) (4)	30 Sep 2020 22:38:17
User entered 'percent'	DeEnna Wedding (b) (4) (b) (4)	30 Sep 2020 18:34:10

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 08:13:30
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:13
User signature succeeded.	David Diemert (b) (4) (b) (4)	30 Sep 2020 22:38:17
User entered 'once daily (QD)'	DeEnna Wedding (b) (4) (b) (4)	30 Sep 2020 18:34:10

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 08:13:30
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:13
User signature succeeded.	David Diemert (b) (4) (b) (4)	30 Sep 2020 22:38:17
User entered empty.	DeEnna Wedding (b) (4) (b) (4)	30 Sep 2020 18:34:10

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 08:13:30
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:13
User signature succeeded.	David Diemert (b) (4) (b) (4)	30 Sep 2020 22:38:17
User entered 'Topical (TOPICAL)'	DeEnna Wedding (b) (4) (b) (4)	30 Sep 2020 18:34:10

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 08:13:30
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:13
User signature succeeded.	David Diemert (b) (4) (b) (4)	30 Sep 2020 22:38:17
User entered empty.	DeEnna Wedding (b) (4) (b) (4)	30 Sep 2020 18:34:10

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 08:13:30
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:13
User signature succeeded.	David Diemert (b) (4) (b) (4)	30 Sep 2020 22:38:17
User entered '26 Sep 2020'	DeEnna Wedding (b) (4) (b) (4)	30 Sep 2020 18:34:10

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 08:13:30
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:13
User signature succeeded.	David Diemert (b) (4) (b) (4)	30 Sep 2020 22:38:17
User entered '0'	DeEnna Wedding (b) (4) (b) (4)	30 Sep 2020 18:34:10

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 08:13:30
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:13
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Oct 2020 18:32:30
Signature has been broken.	Erika Faust (b) (4) (b) (4)	21 Oct 2020 16:08:52
User entered 'No (N)' reason for change: New Information	Erika Faust (b) (4) (b) (4)	21 Oct 2020 16:08:52
User signature succeeded.	David Diemert (b) (4) (b) (4)	30 Sep 2020 22:38:17
User entered 'Yes (Y)'	DeEnna Wedding (b) (4) (b) (4)	30 Sep 2020 18:34:10

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 08:13:30
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:13
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Oct 2020 18:32:30
Signature has been broken.	Erika Faust (b) (4) (b) (4)	21 Oct 2020 16:08:52
User entered '2 Oct 2020' reason for change: New Information	Erika Faust (b) (4) (b) (4)	21 Oct 2020 16:08:52
User signature succeeded.	David Diemert (b) (4) (b) (4)	30 Sep 2020 22:38:17
User entered empty.	DeEnna Wedding (b) (4) (b) (4)	30 Sep 2020 18:34:10

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US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 08:13:30
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:13
User signature succeeded.	David Diemert (b) (4) (b) (4)	30 Sep 2020 22:38:17
User entered 'No (N)'	DeEnna Wedding (b) (4) (b) (4)	30 Sep 2020 18:34:10

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 08:13:30
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:13
User entered '1'	System	30 Sep 2020 18:34:10

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US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 08:13:30
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:13
User entered '1'	System	30 Sep 2020 18:34:10

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US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 08:13:30
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:13
User entered '804 (804)'	System	30 Sep 2020 18:34:10

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US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 08:13:30
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:03
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Nov 2020 04:10:23
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)	19 Nov 2020 17:38:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 17:38:00
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)	19 Nov 2020 17:23:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 17:23:00
Data point term sent to Coder	System	19 Nov 2020 17:22:25
User entered 'Influenza Vaccination'	(b) (4), (b) (6)	19 Nov 2020 17:21:34

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 08:13:30
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:03
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Nov 2020 04:10:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Nov 2020 17:21:34

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 08:13:30
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:03
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Nov 2020 04:10:23
User entered 'Flu Prevention'	(b) (4), (b) (6)	19 Nov 2020 17:21:34

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 08:13:30
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:03
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Nov 2020 04:10:23
User entered '0.5'	(b) (4), (b) (6)	19 Nov 2020 17:21:34

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 08:13:30
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:03
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Nov 2020 04:10:23
User entered 'mL (mL)'	(b) (4), (b) (6)	19 Nov 2020 17:21:34

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 08:13:30
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:03
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Nov 2020 04:10:23
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 17:21:34

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 08:13:30
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:03
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Nov 2020 04:10:23
User entered 'once (ONCE)'	(b) (4), (b) (6)	19 Nov 2020 17:21:34

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 08:13:30
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:03
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Nov 2020 04:10:23
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 17:21:34

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 08:13:30
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:03
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Nov 2020 04:10:23
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4), (b) (6)	19 Nov 2020 17:21:34

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 08:13:30
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:03
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Nov 2020 04:10:23
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 17:21:34

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 08:13:30
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:03
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Nov 2020 04:10:23
User entered '24 Oct 2020'	(b) (4), (b) (6)	19 Nov 2020 17:21:34

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US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 08:13:30
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:03
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Nov 2020 04:10:23
User entered '0'	(b) (4), (b) (6)	19 Nov 2020 17:21:34

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 08:13:30
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:03
User signature succeeded.	David Diemert (b) (4) (b) (4)	18 Dec 2020 16:14:51
Signature has been broken.	(b) (4), (b) (6)	17 Dec 2020 16:32:40
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	17 Dec 2020 16:32:40
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Nov 2020 04:10:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Nov 2020 17:21:34

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 08:13:30
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:03
User signature succeeded.	David Diemert (b) (4) (b) (4)	18 Dec 2020 16:14:51
Signature has been broken.	(b) (4), (b) (6)	17 Dec 2020 16:32:40
User entered '24 Oct 2020' reason for change: New Information	(b) (4), (b) (6)	17 Dec 2020 16:32:40
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Nov 2020 04:10:23
User entered empty.	(b) (4), (b) (6)	19 Nov 2020 17:21:34

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 08:13:30
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:03
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Nov 2020 04:10:23
User entered 'No (N)'	(b) (4), (b) (6)	19 Nov 2020 17:21:34

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 08:13:30
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:03
User entered empty.	System	19 Nov 2020 17:21:34

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 08:13:30
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:03
User entered empty.	System	19 Nov 2020 17:21:34

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 08:13:30
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:03
User entered empty.	System	19 Nov 2020 17:21:34

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 08:13:30
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:03
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Dec 2020 22:58:26
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 17:33:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 17:33:50
Data point term sent to Coder	System	18 Dec 2020 16:29:15
User entered 'Metoprolol'	Erika Faust (b) (4) (b) (4)	18 Dec 2020 16:28:59

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 08:13:30
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:03
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Dec 2020 22:58:26
User entered 'No (N)'	Erika Faust (b) (4) (b) (4)	18 Dec 2020 16:28:59

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 08:13:30
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:03
Query 'Per DM CLR: Please note that there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' canceled (Site from DM).	(b) (4), (b) (6)	30 Jan 2021 06:48:44
User opened query 'Per DM CLR: Please note that there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	30 Jan 2021 06:48:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Dec 2020 22:58:26
User entered 'Atrial fibrillation'	Erika Faust (b) (4) (b) (4)	18 Dec 2020 16:28:59

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US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 08:13:30
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:03
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Dec 2020 22:58:26
User entered '50'	Erika Faust (b) (4) (b) (4)	18 Dec 2020 16:28:59

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 08:13:30
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:03
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Dec 2020 22:58:26
User entered 'mg (mg)'	Erika Faust (b) (4) (b) (4)	18 Dec 2020 16:28:59

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 08:13:30
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:03
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Dec 2020 22:58:26
User entered empty.	Erika Faust (b) (4) (b) (4)	18 Dec 2020 16:28:59

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 08:13:30
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:03
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Dec 2020 22:58:26
User entered 'twice daily (BID)'	Erika Faust (b) (4) (b) (4)	18 Dec 2020 16:28:59

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 08:13:30
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:03
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Dec 2020 22:58:26
User entered empty.	Erika Faust (b) (4) (b) (4)	18 Dec 2020 16:28:59

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US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 08:13:30
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:03
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Dec 2020 22:58:26
User entered 'Oral (ORAL)'	Erika Faust (b) (4) (b) (4)	18 Dec 2020 16:28:59

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US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 08:13:30
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:03
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Dec 2020 22:58:26
User entered empty.	Erika Faust (b) (4) (b) (4)	18 Dec 2020 16:28:59

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 08:13:30
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:03
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Dec 2020 22:58:26
User entered '15 Dec 2020'	Erika Faust (b) (4) (b) (4)	18 Dec 2020 16:28:59

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 08:13:30
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:03
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Dec 2020 22:58:26
User entered '0'	Erika Faust (b) (4) (b) (4)	18 Dec 2020 16:28:59

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 08:13:30
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:03
User signature succeeded.	David Diemert (b) (4) (b) (4)	13 Jan 2021 03:41:29
Signature has been broken.	Erika Faust (b) (4) (b) (4)	08 Jan 2021 18:29:30
User entered 'No (N)' reason for change: New Information	Erika Faust (b) (4) (b) (4)	08 Jan 2021 18:29:30
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Dec 2020 22:58:26
User entered 'Yes (Y)'	Erika Faust (b) (4) (b) (4)	18 Dec 2020 16:28:59

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 08:13:30
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:03
User signature succeeded.	David Diemert (b) (4) (b) (4)	13 Jan 2021 03:41:29
Signature has been broken.	Erika Faust (b) (4) (b) (4)	08 Jan 2021 18:29:30
User entered '23 Dec 2020' reason for change: New Information	Erika Faust (b) (4) (b) (4)	08 Jan 2021 18:29:30
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Dec 2020 22:58:26
User entered empty.	Erika Faust (b) (4) (b) (4)	18 Dec 2020 16:28:59

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 08:13:30
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:03
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Dec 2020 22:58:26
User entered 'No (N)'	Erika Faust (b) (4) (b) (4)	18 Dec 2020 16:28:59

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 08:13:30
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:03
User entered '2'	System	18 Dec 2020 16:28:59

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 08:13:30
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:03
User entered '1'	System	18 Dec 2020 16:28:59

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US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 08:13:30
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:03
User entered '804 (804)'	System	18 Dec 2020 16:28:59

FDA-CBER-2022-1614-2661687

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 08:13:30
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:14
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Dec 2020 22:58:26
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 18:55:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 18:55:37
Data point term sent to Coder	System	18 Dec 2020 16:30:17
User entered 'Oxycodone'	Erika Faust (b) (4) (b) (4)	18 Dec 2020 16:29:43

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 08:13:30
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:14
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Dec 2020 22:58:26
User entered 'No (N)'	Erika Faust (b) (4) (b) (4)	18 Dec 2020 16:29:43

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 08:13:30
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:14
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Dec 2020 22:58:26
User entered 'Pain secondary to cholystectomy'	Erika Faust (b) (4) (b) (4)	18 Dec 2020 16:29:43

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 08:13:30
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:14
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Dec 2020 22:58:26
User entered '5'	Erika Faust (b) (4) (b) (4)	18 Dec 2020 16:29:43

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 08:13:30
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:14
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Dec 2020 22:58:26
User entered 'mg (mg)'	Erika Faust (b) (4) (b) (4)	18 Dec 2020 16:29:43

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 08:13:30
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:14
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Dec 2020 22:58:26
User entered empty.	Erika Faust (b) (4) (b) (4)	18 Dec 2020 16:29:43

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 08:13:30
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:14
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Dec 2020 22:58:26
User entered 'once (ONCE)'	Erika Faust (b) (4) (b) (4)	18 Dec 2020 16:29:43

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 08:13:30
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:14
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Dec 2020 22:58:26
User entered empty.	Erika Faust (b) (4) (b) (4)	18 Dec 2020 16:29:43

FDA-CBER-2022-1614-2661695

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 08:13:30
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:14
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Dec 2020 22:58:26
User entered 'Oral (ORAL)'	Erika Faust (b) (4) (b) (4)	18 Dec 2020 16:29:43

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 08:13:30
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:14
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Dec 2020 22:58:26
User entered empty.	Erika Faust (b) (4) (b) (4)	18 Dec 2020 16:29:43

FDA-CBER-2022-1614-2661697

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 08:13:30
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:14
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Dec 2020 22:58:26
User entered '16 Dec 2020'	Erika Faust (b) (4) (b) (4)	18 Dec 2020 16:29:43

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 08:13:30
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:14
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Dec 2020 22:58:26
User entered '0'	Erika Faust (b) (4) (b) (4)	18 Dec 2020 16:29:43

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 08:13:30
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:14
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Dec 2020 22:58:26
User entered 'No (N)'	Erika Faust (b) (4) (b) (4)	18 Dec 2020 16:29:43

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 08:13:30
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:14
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Dec 2020 22:58:26
User entered '16 Dec 2020'	Erika Faust (b) (4) (b) (4)	18 Dec 2020 16:29:43

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 08:13:30
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:14
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Dec 2020 22:58:26
User entered 'No (N)'	Erika Faust (b) (4) (b) (4)	18 Dec 2020 16:29:43

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 08:13:30
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:14
User entered empty.	System	18 Dec 2020 16:29:43

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 08:13:30
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:14
User entered empty.	System	18 Dec 2020 16:29:43

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 08:13:30
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:14
User entered empty.	System	18 Dec 2020 16:29:43

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 08:13:30
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:20
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Feb 2021 13:26:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Feb 2021 13:26:52
Data point term sent to Coder	System	10 Feb 2021 22:32:39
User entered 'Metoprolol'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:32:16

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 08:13:30
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:20
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered 'No (N)'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:32:16

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 08:13:30
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:20
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered 'Atrial flutter'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:32:16

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 08:13:30
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:20
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered '5'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:32:16

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 08:13:30
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:20
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered 'mg (mg)'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:32:16

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 08:13:30
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:20
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered empty.	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:32:16

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 08:13:30
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:20
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered 'once (ONCE)'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:32:16

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 08:13:30
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:20
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered empty.	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:32:16

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 08:13:30
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:20
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered 'Intravenous (INTRAVENOUS)'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:32:16

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 08:13:30
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:20
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered empty.	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:32:16

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 08:13:30
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:20
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered '04 Feb 2021' reason for change: Data Entry Error	Erika Faust (b) (4) (b) (4)	11 Feb 2021 16:53:41
User entered '4 Feb 2021'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:32:16

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US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 08:13:30
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:20
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered '0'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:32:16

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 08:13:30
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:20
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered 'No (N)'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:32:16

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 08:13:30
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:20
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered '04 Feb 2021' reason for change: Data Entry Error	Erika Faust (b) (4) (b) (4)	11 Feb 2021 16:53:41
User entered '4 Feb 2021'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:32:16

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 08:13:30
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:20
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered 'No (N)'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:32:16

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 08:13:30
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:20
User entered empty.	System	10 Feb 2021 22:32:16

FDA-CBER-2022-1614-2661721

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 08:13:30
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:20
User entered empty.	System	10 Feb 2021 22:32:16

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 08:13:30
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:20
User entered empty.	System	10 Feb 2021 22:32:16

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 08:13:30
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:26
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Feb 2021 22:34:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Feb 2021 22:34:39
Data point term sent to Coder	System	10 Feb 2021 22:33:44
User entered 'Metoprolol'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:32:53

FDA-CBER-2022-1614-2661724

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 08:13:30
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:26
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered 'No (N)'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:32:53

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 08:13:30
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:26
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered 'Atrial flutter'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:32:53

FDA-CBER-2022-1614-2661726

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 08:13:30
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:26
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered '50'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:32:53

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 08:13:30
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:26
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered 'mg (mg)'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:32:53

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 08:13:30
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:26
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered empty.	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:32:53

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 08:13:30
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:26
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered 'twice daily (BID)'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:32:53

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 08:13:30
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:26
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered empty.	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:32:53

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 08:13:30
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:26
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered 'Oral (ORAL)'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:32:53

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 08:13:30
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:26
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered empty.	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:32:53

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 08:13:30
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:26
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered '04 Feb 2021' reason for change: Data Entry Error	Erika Faust (b) (4) (b) (4)	11 Feb 2021 16:54:02
User entered '4 Feb 2021'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:32:53

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 08:13:30
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:26
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered '0'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:32:53

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 08:13:30
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:26
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered 'No (N)'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:32:53

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 08:13:30
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:26
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered '08 Feb 2021' reason for change: Data Entry Error	Erika Faust (b) (4) (b) (4)	11 Feb 2021 16:54:02
User entered '8 Feb 2021'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:32:53

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US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 08:13:30
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:26
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered 'No (N)'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:32:53

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 08:13:30
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:26
User entered '2'	System	10 Feb 2021 22:32:53

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 08:13:30
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:26
User entered '1'	System	10 Feb 2021 22:32:53

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 08:13:30
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:26
User entered '804 (804)'	System	10 Feb 2021 22:32:53

FDA-CBER-2022-1614-2661741

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 08:13:30
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:35
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE, PRODUCTSYNONYM: LASIX [FUROSEMIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Feb 2021 13:17:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Feb 2021 13:17:52
Data point term sent to Coder	System	10 Feb 2021 22:33:44
User entered 'Lasix'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:33:29

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 08:13:30
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:35
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered 'No (N)'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:33:29

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 08:13:30
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:35
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered 'Acute heart failure'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:33:29

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 08:13:30
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:35
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered '20'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:33:29

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 08:13:30
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:35
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered 'mg (mg)'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:33:29

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 08:13:30
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:35
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered empty.	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:33:29

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 08:13:30
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:35
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered 'once (ONCE)'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:33:29

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 08:13:30
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:35
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered empty.	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:33:29

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 08:13:30
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:35
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered 'Intravenous (INTRAVENOUS)'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:33:29

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 08:13:30
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:35
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered empty.	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:33:29

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 08:13:30
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:35
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered '04 Feb 2021' reason for change: Data Entry Error	Erika Faust (b) (4) (b) (4)	11 Feb 2021 16:54:25
User entered '4 Feb 2021'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:33:29

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 08:13:30
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:35
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered '0'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:33:29

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 08:13:30
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:35
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered 'No (N)'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:33:29

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 08:13:30
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:35
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered '04 Feb 2021' reason for change: Data Entry Error	Erika Faust (b) (4) (b) (4)	11 Feb 2021 16:54:25
User entered '4 Feb 2021'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:33:29

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 08:13:30
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:35
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered 'No (N)'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:33:29

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 08:13:30
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:35
User entered empty.	System	10 Feb 2021 22:33:29

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 08:13:30
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:35
User entered empty.	System	10 Feb 2021 22:33:29

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 08:13:30
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:35
User entered empty.	System	10 Feb 2021 22:33:29

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 08:13:30
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Feb 2021 00:39:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Feb 2021 00:39:43
Data point term sent to Coder	System	10 Feb 2021 22:34:44
User entered 'Atorvastatin'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:34:11

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 08:13:30
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered 'Yes (Y)'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:34:11

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 08:13:30
Indication

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered 'Cardiac health/ stroke prevention'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:34:11

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 08:13:30
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered '40'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:34:11

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 08:13:30
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered 'mg (mg)'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:34:11

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 08:13:30
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered empty.	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:34:11

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 08:13:30
Frequency

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered 'other (OTHER)'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:34:11

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 08:13:30
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered 'QHS (nightly)'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:34:11

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 08:13:30
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered 'Oral (ORAL)'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:34:11

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 08:13:30
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered empty.	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:34:11

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 08:13:30
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered '04 Feb 2021' reason for change: Data Entry Error	Erika Faust (b) (4) (b) (4)	11 Feb 2021 16:54:45
User entered '4 Feb 2021'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:34:11

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 08:13:30
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered '0'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:34:11

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 08:13:30
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered 'Yes (Y)'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:34:11

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 08:13:30
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered empty.	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:34:11

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 08:13:30
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered 'No (N)'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:34:11

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 08:13:30
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	10 Feb 2021 22:34:11

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 08:13:30
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	10 Feb 2021 22:34:11

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 08:13:30
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered empty.	System	10 Feb 2021 22:34:11

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 08:13:30
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
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)	11 Feb 2021 00:39:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Feb 2021 00:39:43
Data point term sent to Coder	System	10 Feb 2021 22:35:47
User entered 'Aspirin'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:34:47

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US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 08:13:30
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered 'Yes (Y)'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:34:47

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 08:13:30
Indication

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered 'Cardiac health/ stroke prevention'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:34:47

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 08:13:30
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered '81'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:34:47

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 08:13:30
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered 'mg (mg)'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:34:47

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 08:13:30
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered empty.	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:34:47

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 08:13:30
Frequency

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered 'once daily (QD)'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:34:47

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US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 08:13:30
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered empty.	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:34:47

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 08:13:30
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered 'Oral (ORAL)'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:34:47

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 08:13:30
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered empty.	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:34:47

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 08:13:30
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered '04 Feb 2021' reason for change: Data Entry Error	Erika Faust (b) (4) (b) (4)	11 Feb 2021 16:54:59
User entered '4 Feb 2021'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:34:47

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 08:13:30
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered '0'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:34:47

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 08:13:30
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered 'Yes (Y)'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:34:47

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 08:13:30
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered empty.	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:34:47

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 08:13:30
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered 'No (N)'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:34:47

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 08:13:30
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	10 Feb 2021 22:34:47

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 08:13:30
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	10 Feb 2021 22:34:47

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 08:13:30
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Feb 2021 22:34:47

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 08:13:30
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:44
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, NON-SELECTIVE, PRODUCT: SOTALOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 15:54:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 15:54:57
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
Data point term sent to Coder	System	10 Feb 2021 22:35:45
User entered 'Sotalol'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:35:20

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US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 08:13:30
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:44
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered 'No (N)'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:35:20

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 08:13:30
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:44
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered 'Atrial flutter'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:35:20

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 08:13:30
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:44
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered '80'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:35:20

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 08:13:30
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:44
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered 'mg (mg)'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:35:20

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 08:13:30
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:44
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered empty.	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:35:20

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 08:13:30
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:44
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User closed query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	10 Feb 2021 22:37:37
Query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' answered by data change (Site from System).	System	10 Feb 2021 22:37:37
User entered 'twice daily (BID)' reason for change: Data Entry Error	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:37:37
User opened query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	10 Feb 2021 22:35:20
User entered 'once (ONCE)'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:35:20

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 08:13:30
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:44
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered empty.	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:35:20

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 08:13:30
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:44
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered 'Intravenous (INTRAVENOUS)'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:35:20

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 08:13:30
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:44
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered empty.	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:35:20

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 08:13:30
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:44
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered '07 Feb 2021' reason for change: Data Entry Error	Erika Faust (b) (4) (b) (4)	11 Feb 2021 16:55:19
User entered '7 Feb 2021'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:35:20

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US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 08:13:30
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:44
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered '0'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:35:20

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 08:13:30
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:44
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered 'No (N)'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:35:20

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 08:13:30
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:44
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered '08 Feb 2021' reason for change: Data Entry Error	Erika Faust (b) (4) (b) (4)	11 Feb 2021 16:55:19
User entered '8 Feb 2021'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:35:20

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US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 08:13:30
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:44
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered 'No (N)'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:35:20

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 08:13:30
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:44
User entered '2'	System	10 Feb 2021 22:37:37
User entered empty.	System	10 Feb 2021 22:35:20

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US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 08:13:30
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:44
User entered '1'	System	10 Feb 2021 22:37:37
User entered empty.	System	10 Feb 2021 22:35:20

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 08:13:30
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:44
User entered '804 (804)'	System	10 Feb 2021 22:37:37
User entered empty.	System	10 Feb 2021 22:35:20

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 08:13:30
Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, NON-SELECTIVE, PRODUCT: SOTALOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 15:39:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 15:39:57
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
Data point term sent to Coder	System	10 Feb 2021 22:36:49
User entered 'Sotalol'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:35:58

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US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 08:13:30
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered 'No (N)'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:35:58

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 08:13:30
Indication

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered 'Atrial fluter'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:35:58

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 08:13:30
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered '80'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:35:58

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 08:13:30
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered 'mg (mg)'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:35:58

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 08:13:30
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered empty.	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:35:58

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 08:13:30
Frequency

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered 'twice daily (BID)' reason for change: Data Entry Error	Erika Faust (b) (4) (b) (4)	11 Feb 2021 16:55:42
User entered 'once (ONCE)'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:35:58

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 08:13:30
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered empty.	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:35:58

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 08:13:30
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered 'Oral (ORAL)'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:35:58

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 08:13:30
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered empty.	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:35:58

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 08:13:30
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered '08 Feb 2021' reason for change: Data Entry Error	Erika Faust (b) (4) (b) (4)	11 Feb 2021 16:55:42
User entered '8 Feb 2021'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:35:58

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US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 08:13:30
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered '0'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:35:58

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 08:13:30
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered 'Yes (Y)'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:35:58

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US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 08:13:30
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered empty.	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:35:58

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 08:13:30
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered 'No (N)'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:35:58

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 08:13:30
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '2'	System	11 Feb 2021 16:55:42
User entered empty.	System	10 Feb 2021 22:35:58

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 08:13:30
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	11 Feb 2021 16:55:42
User entered empty.	System	10 Feb 2021 22:35:58

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 08:13:30
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Feb 2021 16:55:42
User entered empty.	System	10 Feb 2021 22:35:58

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 08:13:30
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:27:09
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), COMBINATIONS, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), OTHER COMBINATIONS, PRODUCT: SACUBITRIL VALSARTAN SODIUM HYDRATE, PRODUCTSYNONYM: ENTRESTO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Feb 2021 22:37:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Feb 2021 22:37:40
Data point term sent to Coder	System	10 Feb 2021 22:36:48
User entered 'Entresto'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:36:40

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US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 08:13:30
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:27:09
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered 'No (N)'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:36:40

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 08:13:30
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:27:09
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered 'Acute heart failure'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:36:40

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 08:13:30
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:27:09
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered 'UNK'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:36:40

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 08:13:30
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:27:09
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered 'Other (OTHER)'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:36:40

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 08:13:30
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:27:09
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered 'UNKNOWN'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:36:40

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 08:13:30
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:27:09
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered 'unknown (UNKNOWN)'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:36:40

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 08:13:30
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:27:09
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered empty.	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:36:40

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 08:13:30
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:27:09
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered 'Oral (ORAL)'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:36:40

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 08:13:30
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:27:09
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered empty.	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:36:40

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 08:13:30
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:27:09
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered 'un Feb 2021' reason for change: Data Entry Error	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:39:07
User entered empty.	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:36:40

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 08:13:30
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:27:09
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User closed query 'Start date is provided, however Start date completely unknown is checked. Please correct.' (Site from System).	System	10 Feb 2021 22:39:13
User entered '0' reason for change: Data Entry Error	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:39:13
User opened query 'Start date is provided, however Start date completely unknown is checked. Please correct.' (Site from System).	System	10 Feb 2021 22:39:07
User entered '1'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:36:40

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 08:13:30
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:27:09
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered 'No (N)'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:36:40

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 08:13:30
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:27:09
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	10 Feb 2021 22:38:14
User entered 'un Feb 2021' reason for change: Data Entry Error	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:38:14
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	10 Feb 2021 22:38:09
User closed query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	10 Feb 2021 22:38:09
User entered ' Feb 2021' (non-conformant).	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:38:09
User opened query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	10 Feb 2021 22:37:58
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	10 Feb 2021 22:37:58
User entered empty; reason for change Data Entry Error	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:37:58
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	10 Feb 2021 22:36:59
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	10 Feb 2021 22:36:59
User entered 'un UNK unk' (non-conformant).	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:36:59
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	10 Feb 2021 22:36:52
User closed query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	10 Feb 2021 22:36:52
User entered ' UNK ' (non-conformant).	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:36:52
User opened query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	10 Feb 2021 22:36:40
User entered empty.	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:36:40

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US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 08:13:30
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:27:09
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered 'No (N)'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:36:40

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 08:13:30
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:27:09
User entered empty.	System	10 Feb 2021 22:36:40

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 08:13:30
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:27:09
User entered empty.	System	10 Feb 2021 22:36:40

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 08:13:30
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:27:09
User entered empty.	System	10 Feb 2021 22:36:40

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 08:13:30
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:52
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: VITAMIN K ANTAGONISTS, PRODUCT: WARFARIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 17:36:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 17:36:57
Data point term sent to Coder	System	15 Mar 2021 17:36:27
Coding entries removed.	Elissa Malkin (b) (4) (b) (4)	15 Mar 2021 17:36:04
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: VITAMIN K ANTAGONISTS, PRODUCT: WARFARIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Feb 2021 16:36:26
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Feb 2021 16:36:26
User signature succeeded.	David Diemert (b) (4) (b) (4)	25 Feb 2021 20:43:24
Data point term sent to Coder	System	24 Feb 2021 16:52:29
User entered 'Warfarin'	Erika Faust (b) (4) (b) (4)	24 Feb 2021 16:52:06

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 08:13:30
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:52
User signature succeeded.	David Diemert (b) (4) (b) (4)	25 Feb 2021 20:43:24
User entered 'No (N)'	Erika Faust (b) (4) (b) (4)	24 Feb 2021 16:52:06

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 08:13:30
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:52
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 10:52:42
User signature succeeded.	David Diemert (b) (4) (b) (4)	15 Mar 2021 20:17:40
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' answered with 'updated per medical history' (Site from DM).	Elissa Malkin (b) (4) (b) (4)	15 Mar 2021 17:36:20
Signature has been broken.	Elissa Malkin (b) (4) (b) (4)	15 Mar 2021 17:36:04
User entered 'MITRAL VALVE Replacement' reason for change: Per Query Resolution	Elissa Malkin (b) (4) (b) (4)	15 Mar 2021 17:36:04
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 07:38:12
User signature succeeded.	David Diemert (b) (4) (b) (4)	25 Feb 2021 20:43:24
User entered 'Mitral valve regurgitation'	Erika Faust (b) (4) (b) (4)	24 Feb 2021 16:52:06

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US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 08:13:30
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:52
User signature succeeded.	David Diemert (b) (4) (b) (4)	25 Feb 2021 20:43:24
User entered '5'	Erika Faust (b) (4) (b) (4)	24 Feb 2021 16:52:06

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 08:13:30
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:52
User signature succeeded.	David Diemert (b) (4) (b) (4)	25 Feb 2021 20:43:24
User entered 'mg (mg)'	Erika Faust (b) (4) (b) (4)	24 Feb 2021 16:52:06

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 08:13:30
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:52
User signature succeeded.	David Diemert (b) (4) (b) (4)	25 Feb 2021 20:43:24
User entered empty.	Erika Faust (b) (4) (b) (4)	24 Feb 2021 16:52:06

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 08:13:30
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:52
User signature succeeded.	David Diemert (b) (4) (b) (4)	25 Feb 2021 20:43:24
User entered 'once daily (QD)'	Erika Faust (b) (4) (b) (4)	24 Feb 2021 16:52:06

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 08:13:30
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:52
User signature succeeded.	David Diemert (b) (4) (b) (4)	25 Feb 2021 20:43:24
User entered empty.	Erika Faust (b) (4) (b) (4)	24 Feb 2021 16:52:06

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US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 08:13:30
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:52
User signature succeeded.	David Diemert (b) (4) (b) (4)	25 Feb 2021 20:43:24
User entered 'Oral (ORAL)'	Erika Faust (b) (4) (b) (4)	24 Feb 2021 16:52:06

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 08:13:30
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:52
User signature succeeded.	David Diemert (b) (4) (b) (4)	25 Feb 2021 20:43:24
User entered empty.	Erika Faust (b) (4) (b) (4)	24 Feb 2021 16:52:06

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 08:13:30
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:52
User signature succeeded.	David Diemert (b) (4) (b) (4)	25 Feb 2021 20:43:24
User entered '05 Feb 2021'	Erika Faust (b) (4) (b) (4)	24 Feb 2021 16:52:06

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 08:13:30
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:52
User signature succeeded.	David Diemert (b) (4) (b) (4)	25 Feb 2021 20:43:24
User entered '0'	Erika Faust (b) (4) (b) (4)	24 Feb 2021 16:52:06

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 08:13:30
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:52
User signature succeeded.	David Diemert (b) (4) (b) (4)	25 Feb 2021 20:43:24
User entered 'No (N)'	Erika Faust (b) (4) (b) (4)	24 Feb 2021 16:52:06

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 08:13:30
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:52
User signature succeeded.	David Diemert (b) (4) (b) (4)	25 Feb 2021 20:43:24
User entered '07 Feb 2021'	Erika Faust (b) (4) (b) (4)	24 Feb 2021 16:52:06

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 08:13:30
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:52
User signature succeeded.	David Diemert (b) (4) (b) (4)	25 Feb 2021 20:43:24
User entered 'No (N)'	Erika Faust (b) (4) (b) (4)	24 Feb 2021 16:52:06

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 08:13:30
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:52
User entered '1'	System	24 Feb 2021 16:52:06

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 08:13:30
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:52
User entered '1'	System	24 Feb 2021 16:52:06

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 08:13:30
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:52
User entered '804 (804)'	System	24 Feb 2021 16:52:06

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US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 10 Jun 2021 08:13:30
Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: VITAMIN K ANTAGONISTS, PRODUCT: WARFARIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 17:37:58
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 17:37:58
Data point term sent to Coder	System	15 Mar 2021 17:37:28
Coding entries removed.	Elissa Malkin (b) (4) (b) (4)	15 Mar 2021 17:36:45
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: VITAMIN K ANTAGONISTS, PRODUCT: WARFARIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Feb 2021 16:36:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Feb 2021 16:36:27
User signature succeeded.	David Diemert (b) (4) (b) (4)	25 Feb 2021 20:43:24
Data point term sent to Coder	System	24 Feb 2021 16:53:30
User entered 'Warfarin'	Erika Faust (b) (4) (b) (4)	24 Feb 2021 16:52:36

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US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 10 Jun 2021 08:13:30
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	25 Feb 2021 20:43:24
User entered 'No (N)'	Erika Faust (b) (4) (b) (4)	24 Feb 2021 16:52:36

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 10 Jun 2021 08:13:30
Indication

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 10:52:49
User signature succeeded.	David Diemert (b) (4) (b) (4)	15 Mar 2021 20:17:40
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' answered with 'updated - medical history' (Site from DM).	Elissa Malkin (b) (4) (b) (4)	15 Mar 2021 17:37:07
Signature has been broken.	Elissa Malkin (b) (4) (b) (4)	15 Mar 2021 17:36:45
User entered 'MITRAL VALVE replacement' reason for change: Per Query Resolution	Elissa Malkin (b) (4) (b) (4)	15 Mar 2021 17:36:45
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 07:38:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	25 Feb 2021 20:43:24
User entered 'Mitral valve regurgitation'	Erika Faust (b) (4) (b) (4)	24 Feb 2021 16:52:36

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 10 Jun 2021 08:13:30
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	25 Feb 2021 20:43:24
User entered '6'	Erika Faust (b) (4) (b) (4)	24 Feb 2021 16:52:36

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 10 Jun 2021 08:13:30
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	25 Feb 2021 20:43:24
User entered 'mg (mg)'	Erika Faust (b) (4) (b) (4)	24 Feb 2021 16:52:36

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 10 Jun 2021 08:13:30
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	25 Feb 2021 20:43:24
User entered empty.	Erika Faust (b) (4) (b) (4)	24 Feb 2021 16:52:36

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 10 Jun 2021 08:13:30
Frequency

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	25 Feb 2021 20:43:24
User entered 'once daily (QD)'	Erika Faust (b) (4) (b) (4)	24 Feb 2021 16:52:36

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 10 Jun 2021 08:13:30
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	25 Feb 2021 20:43:24
User entered empty.	Erika Faust (b) (4) (b) (4)	24 Feb 2021 16:52:36

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 10 Jun 2021 08:13:30
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	25 Feb 2021 20:43:24
User entered 'Oral (ORAL)'	Erika Faust (b) (4) (b) (4)	24 Feb 2021 16:52:36

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 10 Jun 2021 08:13:30
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	25 Feb 2021 20:43:24
User entered empty.	Erika Faust (b) (4) (b) (4)	24 Feb 2021 16:52:36

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 10 Jun 2021 08:13:30
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	25 Feb 2021 20:43:24
User entered '08 Feb 2021'	Erika Faust (b) (4) (b) (4)	24 Feb 2021 16:52:36

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 10 Jun 2021 08:13:30
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	25 Feb 2021 20:43:24
User entered '0'	Erika Faust (b) (4) (b) (4)	24 Feb 2021 16:52:36

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 10 Jun 2021 08:13:30
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	25 Feb 2021 20:43:24
User entered 'Yes (Y)'	Erika Faust (b) (4) (b) (4)	24 Feb 2021 16:52:36

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 10 Jun 2021 08:13:30
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	25 Feb 2021 20:43:24
User entered empty.	Erika Faust (b) (4) (b) (4)	24 Feb 2021 16:52:36

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 10 Jun 2021 08:13:30
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	25 Feb 2021 20:43:24
User entered 'No (N)'	Erika Faust (b) (4) (b) (4)	24 Feb 2021 16:52:36

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 10 Jun 2021 08:13:30
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	24 Feb 2021 16:52:36

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 10 Jun 2021 08:13:30
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	24 Feb 2021 16:52:36

US3542053
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 10 Jun 2021 08:13:30
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Feb 2021 16:52:36

US3542053
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures Summary
Generated On: 10 Jun 2021 08:13:30
Were any concomitant procedures performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:47:56
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:13:42
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Dec 2020 22:58:26
Signature has been broken.	Erika Faust (b) (4) (b) (4)	18 Dec 2020 16:22:01
User entered 'Yes (Y)' reason for change: New Information	Erika Faust (b) (4) (b) (4)	18 Dec 2020 16:22:01
User signature succeeded.	David Diemert (b) (4) (b) (4)	17 Sep 2020 04:18:30
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Sep 2020 16:36:12
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Sep 2020 16:36:12
User entered 'No (N)' reason for change: Data Entry Error	Hannah Yellin (b) (4) (b) (4)	16 Sep 2020 16:36:12
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Aug 2020 17:11:43
User entered empty; reason for change Data Entry Error	Madhu Balachandran (b) (4)	26 Aug 2020 17:11:43
User entered 'Yes (Y)'	Madhu Balachandran (b) (4)	26 Aug 2020 17:11:32

US3542053
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (1)
Generated On: 10 Jun 2021 08:13:30
Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:14:22
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Dec 2020 22:58:26
User entered '14 Dec 2020'	Erika Faust (b) (4) (b) (4)	18 Dec 2020 16:22:22

US3542053
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (1)
Generated On: 10 Jun 2021 08:13:30
Procedure/Surgery

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:14:22
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Dec 2020 22:58:26
User entered 'Cholecystectomy'	Erika Faust (b) (4) (b) (4)	18 Dec 2020 16:22:22

US3542053
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (1)
Generated On: 10 Jun 2021 08:13:30
Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:14:22
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Dec 2020 22:58:26
User entered 'Medical History (MH)'	Erika Faust (b) (4) (b) (4)	18 Dec 2020 16:22:22

US3542053
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (1)
Generated On: 10 Jun 2021 08:13:30
If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:14:22
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Dec 2020 22:58:26
User entered empty.	Erika Faust (b) (4) (b) (4)	18 Dec 2020 16:22:22

FDA-CBER-2022-1614-2661890

US3542053
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (2)
Generated On: 10 Jun 2021 08:13:30
Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:49:59
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:14:22
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Dec 2020 22:58:26
User entered '15 Dec 2020'	Erika Faust (b) (4) (b) (4)	18 Dec 2020 16:23:31

FDA-CBER-2022-1614-2661891

US3542053
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (2)
Generated On: 10 Jun 2021 08:13:30
Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:49:59
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:14:22
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Dec 2020 22:58:26
User entered 'Cardioversion'	Erika Faust (b) (4) (b) (4)	18 Dec 2020 16:23:31

FDA-CBER-2022-1614-2661892

US3542053
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (2)
Generated On: 10 Jun 2021 08:13:30
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:49:59
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:14:22
User signature succeeded.	David Diemert (b) (4) (b) (4)	13 Jan 2021 03:41:29
Signature has been broken.	Erika Faust (b) (4) (b) (4)	08 Jan 2021 18:38:43
User entered 'Adverse Event (AE)' reason for change: New Information	Erika Faust (b) (4) (b) (4)	08 Jan 2021 18:38:43
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Dec 2020 22:58:26
User entered 'Other (OTHER)'	Erika Faust (b) (4) (b) (4)	18 Dec 2020 16:23:31

US3542053
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (2)
Generated On: 10 Jun 2021 08:13:30
If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:49:59
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:14:22
User signature succeeded.	David Diemert (b) (4) (b) (4)	13 Jan 2021 03:41:29
Signature has been broken.	Erika Faust (b) (4) (b) (4)	08 Jan 2021 18:38:43
User entered empty; reason for change New Information	Erika Faust (b) (4) (b) (4)	08 Jan 2021 18:38:43
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Dec 2020 22:58:26
User entered 'Atrial Fibrillation'	Erika Faust (b) (4) (b) (4)	18 Dec 2020 16:23:31

US3542053
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (3)
Generated On: 10 Jun 2021 08:13:30
Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:50:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Mar 2021 14:54:22
User closed query 'Per DM CLR: Please review if this Con Proc was done for AE #4 ATRIAL FLUTTER (04 FEB 2021-08 FEB 2021). If yes, please review the Date of this procedure as it is out of the expected timeframe of its corresponding AE. Please review and reconcile date of procedure, else, there is no AE condition that matches this procedure. Otherwise, clarify as necessary. ' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 08:27:53
Query 'Per DM CLR: Please review if this Con Proc was done for AE #4 ATRIAL FLUTTER (04 FEB 2021-08 FEB 2021). If yes, please review the Date of this procedure as it is out of the expected timeframe of its corresponding AE. Please review and reconcile date of procedure, else, there is no AE condition that matches this procedure. Otherwise, clarify as necessary. ' answered with 'Date corrected.' (Site from DM).	David Diemert (b) (4) (b) (4)	03 Mar 2021 20:41:16
DataPoint Un-verified.	David Diemert (b) (4) (b) (4)	03 Mar 2021 20:41:08
Signature has been broken.	David Diemert (b) (4) (b) (4)	03 Mar 2021 20:41:08
User entered '08 Feb 2021' reason for change: Per Query Resolution	David Diemert (b) (4) (b) (4)	03 Mar 2021 20:41:08
User opened query 'Per DM CLR: Please review if this Con Proc was done for AE #4 ATRIAL FLUTTER (04 FEB 2021-08 FEB 2021). If yes, please review the Date of this procedure as it is out of the expected timeframe of its corresponding AE. Please review and reconcile date of procedure, else, there is no AE condition that matches this procedure. Otherwise, clarify as necessary. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 07:00:06
User signature succeeded.	David Diemert (b) (4) (b) (4)	23 Feb 2021 16:40:27
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 16:17:14
User closed query 'Please confirm. Per source 8Dec2020.' (Site from CRA).	(b) (4), (b) (6)	22 Feb 2021 16:17:10

US3542053
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (3)
Generated On: 10 Jun 2021 08:13:30
Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Query 'Please confirm. Per source 8Dec2020.' answered with 'Corrected' (Site from CRA).	David Diemert (b) (4) (b) (4)	19 Feb 2021 22:33:58
DataPoint Un-verified.	David Diemert (b) (4) (b) (4)	19 Feb 2021 22:33:52
Signature has been broken.	David Diemert (b) (4) (b) (4)	19 Feb 2021 22:33:52
User entered '08 Dec 2020' reason for change: Data Entry Error	David Diemert (b) (4) (b) (4)	19 Feb 2021 22:33:52
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:14:22
User opened query 'Please confirm. Per source 8Dec2020.' (Site from CRA).	(b) (4), (b) (6)	17 Feb 2021 20:14:08
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered '08 Feb 2021' reason for change: Data Entry Error	Erika Faust (b) (4) (b) (4)	11 Feb 2021 16:49:00
User entered '8 Feb 2021'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:29:44

FDA-CBER-2022-1614-2661896

US3542053
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (3)
Generated On: 10 Jun 2021 08:13:30
Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:50:02
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:14:22
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:00:52
User entered 'Cardioversion'	(b) (4) Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:29:44

FDA-CBER-2022-1614-2661897

US3542053
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (3)
Generated On: 10 Jun 2021 08:13:30
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:50:02
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:14:22
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User closed query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	System	10 Feb 2021 22:30:38
User opened query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	System	10 Feb 2021 22:29:44
User entered 'Adverse Event (AE)'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:29:44

US3542053
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (3)
Generated On: 10 Jun 2021 08:13:30
If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:50:02
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:14:22
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:00:52
User entered empty; reason for change Data Entry Error	(b) (4) Caroline Thoreson (b) (4)	10 Feb 2021 22:30:38
User entered 'Atrial flutter'	(b) (4) Caroline Thoreson (b) (4)	10 Feb 2021 22:29:44
	(b) (4)	

FDA-CBER-2022-1614-2661899

US3542053
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (4)
Generated On: 10 Jun 2021 08:13:30
Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:50:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:14:22
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered '05 Feb 2021' reason for change: Data Entry Error	Erika Faust (b) (4) (b) (4)	11 Feb 2021 16:49:10
User entered '5 Feb 2021'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:31:00

FDA-CBER-2022-1614-2661900

US3542053
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (4)
Generated On: 10 Jun 2021 08:13:30
Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:50:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:14:22
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:00:52
User entered 'TTE with doppler'	(b) (4) Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:31:00

FDA-CBER-2022-1614-2661901

US3542053
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (4)
Generated On: 10 Jun 2021 08:13:30
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:50:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:14:22
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:00:52
User entered 'Adverse Event (AE)'	(b) (4) Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:31:00

US3542053
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (4)
Generated On: 10 Jun 2021 08:13:30
If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:50:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:14:22
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:00:52
User entered empty.	(b) (4) Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:31:00

FDA-CBER-2022-1614-2661903

US3542053
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (5)
Generated On: 10 Jun 2021 08:13:30
Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:50:08
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:14:22
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered '07 Feb 2021' reason for change: Data Entry Error	Erika Faust (b) (4) (b) (4)	11 Feb 2021 16:49:16
User entered '7 Feb 2021'	Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:31:13

FDA-CBER-2022-1614-2661904

US3542053
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (5)
Generated On: 10 Jun 2021 08:13:30
Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:50:08
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:14:22
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:00:52
User entered 'TTE with doppler'	(b) (4) Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:31:13

FDA-CBER-2022-1614-2661905

US3542053
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (5)
Generated On: 10 Jun 2021 08:13:30
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:50:08
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:14:22
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:00:52
User entered 'Adverse Event (AE)'	(b) (4) Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:31:13

US3542053
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (5)
Generated On: 10 Jun 2021 08:13:30
If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:50:08
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:14:22
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:00:52
User entered empty.	(b) (4) Caroline Thoreson (b) (4) (b) (4)	10 Feb 2021 22:31:13

FDA-CBER-2022-1614-2661907

US3542053
Folder: SAE USA-US084-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 08:13:30
SAEID

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:13:17
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
Reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 19:23:23
User entered 'USA-US084-2021-MRNA-1273-P301000004'	System	11 Feb 2021 19:22:51

US3542053
Folder: SAE USA-US084-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 08:13:30
Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:13:17
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:00:52
Reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 19:23:23
User entered 'Yes (Y)'	System	11 Feb 2021 19:22:51

US3542053
Folder: SAE USA-US084-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 08:13:30
Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:13:17
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:00:52
Reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 19:23:23
User entered 'No (N)'	System	11 Feb 2021 19:22:51

US3542053
Folder: SAE USA-US084-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 08:13:30
Life threatening

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:13:17
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:00:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 19:23:23
User entered 'No (N)'	System	11 Feb 2021 19:22:51

US3542053
Folder: SAE USA-US084-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 08:13:30
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:13:17
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:00:52
Reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 19:23:23
User entered 'Yes (Y)'	System	11 Feb 2021 19:22:51

US3542053
Folder: SAE USA-US084-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 08:13:30
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:13:17
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:00:52
Reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 19:23:23
User entered 'No (N)'	System	11 Feb 2021 19:22:51

US3542053
Folder: SAE USA-US084-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 08:13:30
Congenital anomaly or birth defect

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:13:17
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
Reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 19:23:23
User entered 'No (N)'	System	11 Feb 2021 19:22:51

US3542053
Folder: SAE USA-US084-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 08:13:30
Other medically important event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:13:17
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:00:52
Reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 19:23:23
User entered 'No (N)'	System	11 Feb 2021 19:22:51

US3542053
Folder: SAE USA-US084-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 08:13:30
Investigator's First Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:13:17
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:00:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 19:23:23
User entered 'David'	System	11 Feb 2021 19:22:51

US3542053
Folder: SAE USA-US084-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 08:13:30
Investigator's Last Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:13:17
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
Reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 19:23:23
User entered 'Diemert'	System	11 Feb 2021 19:22:51

FDA-CBER-2022-1614-2661917

US3542053
Folder: SAE USA-US084-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 08:13:30
Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:13:17
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:00:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 19:23:23
User entered '2300 Eye Street NW'	System	11 Feb 2021 19:22:51

FDA-CBER-2022-1614-2661918

US3542053
Folder: SAE USA-US084-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 08:13:30
Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:13:17
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:00:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 19:23:23
User entered 'Washington'	System	11 Feb 2021 19:22:51

FDA-CBER-2022-1614-2661919

US3542053
Folder: SAE USA-US084-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 08:13:30
Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:13:17
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:00:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 19:23:23
User entered '20037'	System	11 Feb 2021 19:22:51

FDA-CBER-2022-1614-2661920

US3542053
Folder: SAE USA-US084-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 08:13:30
Investigator Country

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:15:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:13:17
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:00:52
User entered 'US'	(b) (4) System	11 Feb 2021 19:23:47

FDA-CBER-2022-1614-2661921

US3542053
Folder: SAE USA-US084-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 08:13:30
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	23 Feb 2021 16:40:27
Signature has been broken.	System	22 Feb 2021 18:15:14
User entered '2'	System	22 Feb 2021 18:15:14
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered '1'	System	11 Feb 2021 19:23:47

US3542053
Folder: SAE USA-US084-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 08:13:30
SAEID

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:13:17
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
Reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 19:23:23
User entered 'USA-US084-2021-MRNA-1273-P301000004'	System	11 Feb 2021 19:22:51

US3542053
Folder: SAE USA-US084-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 08:13:30
Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:13:17
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:00:52
Reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 19:23:23
User entered 'Yes (Y)'	System	11 Feb 2021 19:22:51

US3542053
Folder: SAE USA-US084-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 08:13:30
Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:13:17
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:00:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 19:23:23
User entered 'No (N)'	System	11 Feb 2021 19:22:51

FDA-CBER-2022-1614-2661925

US3542053
Folder: SAE USA-US084-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 08:13:30
Life threatening

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:13:17
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
Reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 19:23:23
User entered 'No (N)'	System	11 Feb 2021 19:22:51

US3542053
Folder: SAE USA-US084-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 08:13:30
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:13:17
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:00:52
Reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 19:23:23
User entered 'Yes (Y)'	System	11 Feb 2021 19:22:51

US3542053
Folder: SAE USA-US084-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 08:13:30
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:13:17
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:00:52
Reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 19:23:23
User entered 'No (N)'	System	11 Feb 2021 19:22:51

FDA-CBER-2022-1614-2661928

US3542053
Folder: SAE USA-US084-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 08:13:30
Congenital anomaly or birth defect

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:13:17
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:00:52
Reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 19:23:23
User entered 'No (N)'	System	11 Feb 2021 19:22:51

US3542053
Folder: SAE USA-US084-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 08:13:30
Other medically important event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:13:17
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:00:52
Reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 19:23:23
User entered 'No (N)'	System	11 Feb 2021 19:22:51

FDA-CBER-2022-1614-2661930

US3542053
Folder: SAE USA-US084-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 08:13:30
Investigator's First Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:13:17
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:00:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 19:23:23
User entered 'David'	System	11 Feb 2021 19:22:51

US3542053
Folder: SAE USA-US084-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 08:13:30
Investigator's Last Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:13:17
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:00:52
Reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 19:23:23
User entered 'Diemert'	System	11 Feb 2021 19:22:51

FDA-CBER-2022-1614-2661932

US3542053
Folder: SAE USA-US084-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 08:13:30
Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:13:17
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:00:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 19:23:23
User entered '2300 Eye Street NW'	System	11 Feb 2021 19:22:51

FDA-CBER-2022-1614-2661933

US3542053
Folder: SAE USA-US084-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 08:13:30
Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:13:17
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:00:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 19:23:23
User entered 'Washington'	System	11 Feb 2021 19:22:51

FDA-CBER-2022-1614-2661934

US3542053
Folder: SAE USA-US084-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 08:13:30
Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:13:17
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:00:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 19:23:23
User entered '20037'	System	11 Feb 2021 19:22:51

FDA-CBER-2022-1614-2661935

US3542053
Folder: SAE USA-US084-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 08:13:30
Investigator Country

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:15:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:13:17
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:00:52
User entered 'US'	(b) (4) System	11 Feb 2021 19:23:47

FDA-CBER-2022-1614-2661936

US3542053
Folder: SAE USA-US084-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 08:13:30
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	23 Feb 2021 16:40:27
Signature has been broken.	System	22 Feb 2021 18:15:14
User entered '2'	System	22 Feb 2021 18:15:14
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered '1'	System	11 Feb 2021 19:23:47

FDA-CBER-2022-1614-2661937

US3542053
Folder: SAE USA-US084-2021-MRNA-1273-P301000004
Form: Safety Report Form (1)
Generated On: 10 Jun 2021 08:13:30
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:13:17
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:00:52
User entered '11/Feb/2021 14:23'	(b) (4) System	11 Feb 2021 19:23:47

US3542053
Folder: SAE USA-US084-2021-MRNA-1273-P301000004
Form: Safety Report Form (1)
Generated On: 10 Jun 2021 08:13:30
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:15:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:13:17
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered '1'	(b) (4), (b) (6)	11 Feb 2021 19:23:47

FDA-CBER-2022-1614-2661939

US3542053
Folder: SAE USA-US084-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 08:13:30
SAEID

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:13:17
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
Reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 19:23:23
User entered 'USA-US084-2021-MRNA-1273-P301000004'	System	11 Feb 2021 19:22:51

US3542053
Folder: SAE USA-US084-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 08:13:30
Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:13:17
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
Reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 19:23:23
User entered 'Yes (Y)'	System	11 Feb 2021 19:22:51

US3542053
Folder: SAE USA-US084-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 08:13:30
Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:13:17
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:00:52
Reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 19:23:23
User entered 'No (N)'	System	11 Feb 2021 19:22:51

US3542053
Folder: SAE USA-US084-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 08:13:30
Life threatening

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:13:17
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:00:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 19:23:23
User entered 'No (N)'	System	11 Feb 2021 19:22:51

US3542053
Folder: SAE USA-US084-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 08:13:30
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:13:17
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:00:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 19:23:23
User entered 'Yes (Y)'	System	11 Feb 2021 19:22:51

US3542053
Folder: SAE USA-US084-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 08:13:30
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:13:17
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:00:52
Reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 19:23:23
User entered 'No (N)'	System	11 Feb 2021 19:22:51

US3542053
Folder: SAE USA-US084-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 08:13:30
Congenital anomaly or birth defect

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:13:17
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
Reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 19:23:23
User entered 'No (N)'	System	11 Feb 2021 19:22:51

US3542053
Folder: SAE USA-US084-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 08:13:30
Other medically important event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:13:17
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
Reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 19:23:23
User entered 'No (N)'	System	11 Feb 2021 19:22:51

FDA-CBER-2022-1614-2661947

US3542053
Folder: SAE USA-US084-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 08:13:30
Investigator's First Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:13:17
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:00:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 19:23:23
User entered 'David'	System	11 Feb 2021 19:22:51

FDA-CBER-2022-1614-2661948

US3542053
Folder: SAE USA-US084-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 08:13:30
Investigator's Last Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:13:17
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:00:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 19:23:23
User entered 'Diemert'	System	11 Feb 2021 19:22:51

FDA-CBER-2022-1614-2661949

US3542053
Folder: SAE USA-US084-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 08:13:30
Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:13:17
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:00:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 19:23:23
User entered '2300 Eye Street NW'	System	11 Feb 2021 19:22:51

US3542053
Folder: SAE USA-US084-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 08:13:30
Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:13:17
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:00:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 19:23:23
User entered 'Washington'	System	11 Feb 2021 19:22:51

FDA-CBER-2022-1614-2661951

US3542053
Folder: SAE USA-US084-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 08:13:30
Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:13:17
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:00:52
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 19:23:23
User entered '20037'	System	11 Feb 2021 19:22:51

FDA-CBER-2022-1614-2661952

US3542053
Folder: SAE USA-US084-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 08:13:30
Investigator Country

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:15:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 20:13:17
User signature succeeded.	David Diemert (b) (4)	16 Feb 2021 17:00:52
User entered 'US'	(b) (4) System	11 Feb 2021 19:23:47

FDA-CBER-2022-1614-2661953

US3542053
Folder: SAE USA-US084-2021-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 08:13:30
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	23 Feb 2021 16:40:27
Signature has been broken.	System	22 Feb 2021 18:15:14
User entered '2'	System	22 Feb 2021 18:15:14
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Feb 2021 17:00:52
User entered '1'	System	11 Feb 2021 19:23:47

FDA-CBER-2022-1614-2661954

US3542053
Folder: SAE USA-US084-2021-MRNA-1273-P301000004
Form: Safety Report Form (2)
Generated On: 10 Jun 2021 08:13:30
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:53:55
User signature succeeded.	David Diemert (b) (4)	23 Feb 2021 16:40:27
User entered '22/Feb/2021 13:15'	System (b) (4)	22 Feb 2021 18:15:14

FDA-CBER-2022-1614-2661955

US3542053
Folder: SAE USA-US084-2021-MRNA-1273-P301000004
Form: Safety Report Form (2)
Generated On: 10 Jun 2021 08:13:30
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:53:57
User signature succeeded.	David Diemert (b) (4) (b) (4)	23 Feb 2021 16:40:27
User entered '1'	(b) (4), (b) (6)	22 Feb 2021 18:15:14

FDA-CBER-2022-1614-2661956