US3542168 (Prod: George Washington University)

Generated By: (b) (6)

Generated On: 26 Nov 2020 09:37:10

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US3542168
Form: Participant Creation
Data signed: (b) (4) **05 Sep 2020 21:50:51**
Generated On: 26 Nov 2020 09:37:10

Participant ID	US3542168

mRNA-1273-P301 Completion Guidelines

FDA-CBER-2022-1614-6050542

US3542168
Folder: Screening
Form: Visit Date
Data signed: (b) (4) **05 Sep 2020 21:50:51**
Generated On: 26 Nov 2020 09:37:10

Was this visit performed?	Yes ☑ No ☐
Visit date (dd MMM yyyy)	04 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ☑
Folder OID	SCRN

FDA-CBER-2022-1614-6050543

US3542168
Folder: Screening
Form: Demographics
Data signed: (b) (4) **24 Sep 2020 11:50:07**
Generated On: 26 Nov 2020 09:37:10

Date of Birth (MMM yyyy)	(b) (6) 1966
Age	54
Age Units	YEARS
Age (Derived)	54
Sex	Female ☐ Male ■
Ethnicity	Hispanic or Latino ☐ Not Hispanic or Latino ■ Not Reported ☐ Unknown ☐
Race (Check All That Apply)	
White	False
Black	True
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-2022-1614-6050544

US3542168
Folder: Screening
Form: Enrollment
Data signed: (b) (4) **05 Sep 2020 21:50:51**
Generated On: 26 Nov 2020 09:37:10

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

FDA-CBER-2022-1614-6050545

US3542168
Folder: Screening
Form: Inclusion/Exclusion Criteria Summary
Data signed: (b) (4) **05 Sep 2020 21:50:51**
Generated On: 26 Nov 2020 09:37:10

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

FDA-CBER-2022-1614-6050546

US3542168
Folder: Screening
Form: Medical History Summary
Data signed: (b) (4) **24 Sep 2020 11:50:07**
Generated On: 26 Nov 2020 09:37:10

Were any significant conditions reported?	Yes ■ No ☐

FDA-CBER-2022-1614-6050547

US3542168
Folder: Screening
Form: Medical History (1)
Data signed: (b) (4) **01 Oct 2020 04:09:17**
Generated On: 26 Nov 2020 09:37:10

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2018
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 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-6050548

US3542168
Folder: Screening
Form: Medical History (2)
Data signed: (b) (4) **01 Oct 2020 04:09:17**
Generated On: 26 Nov 2020 09:37:10

Condition	SKIN GRAFTS FOR BURN
Start date (dd MMM yyyy)	UN UNK 1992
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ■
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1992
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1992
Start Year (derived)	1992
Stop Month and Year (derived)	JAN 1992
Stop Year (derived)	1992

FDA-CBER-2022-1614-6050549

US3542168
Folder: Screening
Form: Medical History (3)
Data signed: (b) (4) **01 Oct 2020 04:09:17**
Generated On: 26 Nov 2020 09:37:10

Condition	GENERALIZED ANXIETY DISORDER
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes ■ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-6050550

US3542168
Folder: Screening
Form: Medical History (4)
Data signed: (b) (4) **01 Oct 2020 04:09:17**
Generated On: 26 Nov 2020 09:37:10

Condition	DEPRESSION
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes ●
	No ○
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-6050551

US3542168
Folder: Screening
Form: Medical History (5)
Data signed: (b) (4) **01 Oct 2020 04:09:17**
Generated On: 26 Nov 2020 09:37:10

Condition	PTSD
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes ●
	No ○
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-6050552

US3542168
Folder: Screening
Form: Medical History (6)
Data signed: (b) (4) **01 Oct 2020 04:09:17**
Generated On: 26 Nov 2020 09:37:10

Condition	BORDERLINE PERSONALITY DISORDER
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes ■ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-6050553

US3542168
Folder: Screening
Form: Medical History (7)
Data signed: (b) (4) **01 Oct 2020 04:09:17**
Generated On: 26 Nov 2020 09:37:10

Condition	SICKLE CELL DISEASE
Start date (dd MMM yyyy)	UN (b) (6) 1966
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)	(b) (6) 1966
Start Year (derived)	1966
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-6050554

US3542168
Folder: Screening
Form: Medical History (8)
Data signed: (b) (4) **01 Oct 2020 04:09:17**
Generated On: 26 Nov 2020 09:37:10

Condition	ANXIETY DISORDER
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes ☑ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-6050555

US3542168
Folder: Screening
Form: Vital Signs
Generated On: 26 Nov 2020 09:37:10

Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	04 SEP 2020
Time of assessment *(00:00-23:59)*	15:38 (24 HR)
Vital Signs Date and Time (derived)	04 SEP 2020 15:38
Height *(xxx.x)*	68 in
Weight *(xxx.x)*	145 lb
BMI *(xxx.x)*	22.09327 kg/m^2
BMI units	KG/M2
Temperature *(xxx.x)*	ND - Not Done
Route of measurement	Oral ☐ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	ND - Not Done
Pulse units	BPM
Respiratory Rate *(xxx)*	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

FDA-CBER-2022-1614-6050556

US3542168
Folder: Screening
Form: Physical Examination
Data signed: (b) (4) **24 Sep 2020 11:50:07**
Generated On: 26 Nov 2020 09:37:10

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-2022-1614-6050557

US3542168
Folder: Screening
Form: Risk of Exposure
Data signed: (b) (4) **24 Sep 2020 11:50:07**
Generated On: 26 Nov 2020 09:37:10

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

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

FDA-CBER-2022-1614-6050559

US3542168
Folder: Visit 1 Day 1
Form: Visit Date
Data signed: (b) (4) **05 Sep 2020 21:50:51**
Generated On: 26 Nov 2020 09:37:10

Was this visit performed?	Yes ☑ No ☐
Visit date (dd MMM yyyy)	4 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ☑
Folder OID	VISIT1

FDA-CBER-2022-1614-6050560

US3542168
Folder: Visit 1 Day 1
Form: Randomization
Data signed: (b) (4) **24 Sep 2020 11:50:07**
Generated On: 26 Nov 2020 09:37:10

What was the date of randomization? *(dd MMM yyyy)*	04 SEP 2020
What was the participant's randomization number?	111966
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-2022-1614-6050561

US3542168
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Data signed: (b) (4) **24 Sep 2020 11:50:07**
Generated On: 26 Nov 2020 09:37:10

Height	ND - Not Done
Weight	ND - Not Done

FDA-CBER-2022-1614-6050562

US3542168
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Data signed: (b) (4) **24 Sep 2020 11:50:07**
Generated On: 26 Nov 2020 09:37:10

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)*	04 SEP 2020
Time of assessment *(00:00-23:59)*	15:38 (24 HR)
Vital Signs Date and Time (derived)	04 SEP 2020 15:38
Temperature *(xxx.x)*	98.8 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	56 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	154 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	92 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-6050563

US3542168
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Data signed: (b) (4) **24 Sep 2020 11:50:07**
Generated On: 26 Nov 2020 09:37:10

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)*	04 SEP 2020
Time of assessment *(00:00-23:59)*	16:48 (24 HR)
Vital Signs Date and Time (derived)	04 SEP 2020 16:48
Temperature *(xxx.x)*	98.8 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	60 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	144 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	94 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-6050564

US3542168
Folder: Visit 1 Day 1
Form: Physical Examination
Data signed: (b) (4) **24 Sep 2020 11:50:07**
Generated On: 26 Nov 2020 09:37:10

Was the physical examination performed?	Yes ☒ No ☐
Date of examination *(dd MMM yyyy)*	04 SEP 2020

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

FDA-CBER-2022-1614-6050565

US3542168
Folder: Visit 1 Day 1
Form: Exposure
Data signed: (b) (4) **05 Sep 2020 21:50:51**
Generated On: 26 Nov 2020 09:37:10

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)*	4 SEP 2020
What was the treatment time? *(00:00-23:59)*	16:18 (24 HR)
Treatment Date and Time (derived)	4 SEP 2020 16:18
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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US3542168
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Data signed: (b) (4) **24 Sep 2020 11:50:07**
Generated On: 26 Nov 2020 09:37:10

Was the sample collected?	Yes ☑ No ☐
Collection date *(dd MMM yyyy)*	04 SEP 2020
Collection time *(00:00-23:59)*	15:56 (24 HR)
Collection date and time (derived)	04 SEP 2020 15:56

FDA-CBER-2022-1614-6050567

US3542168
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab
Data signed: (b) (4) **24 Sep 2020 11:50:07**
Generated On: 26 Nov 2020 09:37:10

Collection date *(dd MMM yyyy)*			04 SEP 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:58	04 SEP 2020 15:58
Nasopharyngeal Swab 2	No		

FDA-CBER-2022-1614-6050568

US3542168
Folder: Visit 1 Day 1
Form: Continuing
Data signed: (b) (4) **17 Sep 2020 04:28:58**
Generated On: 26 Nov 2020 09:37:10

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

FDA-CBER-2022-1614-6050569

US3542168
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 26 Nov 2020 09:37:10

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**	98.8 °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	04 SEP 2020 16:52
PC Open Date & Time	04 SEP 2020 16:38
PC Close Date & Time	04 SEP 2020 19:08

FDA-CBER-2022-1614-6050570

US3542168
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 26 Nov 2020 09:37:10

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.3 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	04 SEP 2020 20:12
PC Open Date & Time	04 SEP 2020 20:03
PC Close Date & Time	05 SEP 2020 11:59

FDA-CBER-2022-1614-6050571

US3542168
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 26 Nov 2020 09:37:10

TIMEPOINT	DAY 2

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.3 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	05 SEP 2020 13:03
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

FDA-CBER-2022-1614-6050572

US3542168
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 26 Nov 2020 09:37:10

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**	98.6 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	06 SEP 2020 17:00
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

FDA-CBER-2022-1614-6050573

US3542168
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 26 Nov 2020 09:37:10

TIMEPOINT	DAY 4

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.7 °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	07 SEP 2020 13:21
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

FDA-CBER-2022-1614-6050574

US3542168
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 26 Nov 2020 09:37:10

TIMEPOINT	DAY 5

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	97.8 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	08 SEP 2020 13:25
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

FDA-CBER-2022-1614-6050575

US3542168
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 26 Nov 2020 09:37:10

TIMEPOINT	DAY 6

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	98.2 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	09 SEP 2020 12:08
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

FDA-CBER-2022-1614-6050576

US3542168
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 26 Nov 2020 09:37:10

TIMEPOINT	DAY 7

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.4 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	10 SEP 2020 20:30
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

FDA-CBER-2022-1614-6050577

US3542168
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 26 Nov 2020 09:37:10

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	04 SEP 2020 16:53
PC Open Date & Time	04 SEP 2020 16:38
PC Close Date & Time	04 SEP 2020 19:08

FDA-CBER-2022-1614-6050578

US3542168
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 26 Nov 2020 09:37:10

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	04 SEP 2020 20:12
PC Open Date & Time	04 SEP 2020 20:03
PC Close Date & Time	05 SEP 2020 11:59

US3542168
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 26 Nov 2020 09:37:10

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	05 SEP 2020 13:03
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

FDA-CBER-2022-1614-6050580

US3542168
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 26 Nov 2020 09:37:10

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	06 SEP 2020 17:01
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

FDA-CBER-2022-1614-6050581

US3542168
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 26 Nov 2020 09:37:10

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	07 SEP 2020 13:21
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

FDA-CBER-2022-1614-6050582

US3542168
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 26 Nov 2020 09:37:10

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	08 SEP 2020 13:26
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

FDA-CBER-2022-1614-6050583

US3542168
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 26 Nov 2020 09:37:10

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	09 SEP 2020 12:08
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

FDA-CBER-2022-1614-6050584

US3542168
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 26 Nov 2020 09:37:10

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	10 SEP 2020 20:31
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

FDA-CBER-2022-1614-6050585

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-2022-1614-6050586

US3542168
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 26 Nov 2020 09:37:10

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	04 SEP 2020 16:55
PC Open Date & Time	04 SEP 2020 16:38
PC Close Date & Time	04 SEP 2020 19:08

FDA-CBER-2022-1614-6050587

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-2022-1614-6050588

US3542168
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 26 Nov 2020 09:37:10

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	04 SEP 2020 20:13
PC Open Date & Time	04 SEP 2020 20:03
PC Close Date & Time	05 SEP 2020 11:59

FDA-CBER-2022-1614-6050589

US3542168
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 26 Nov 2020 09:37:10

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-2022-1614-6050590

US3542168
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 26 Nov 2020 09:37:10

	Yes ☐
PC Time stamp	05 SEP 2020 13:04
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

FDA-CBER-2022-1614-6050591

US3542168
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 26 Nov 2020 09:37:10

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-2022-1614-6050592

US3542168
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 26 Nov 2020 09:37:10

	Yes ☐
PC Time stamp	06 SEP 2020 17:02
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

FDA-CBER-2022-1614-6050593

US3542168
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 26 Nov 2020 09:37:10

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-2022-1614-6050594

US3542168
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 26 Nov 2020 09:37:10

	Yes ☐
PC Time stamp	07 SEP 2020 13:22
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

FDA-CBER-2022-1614-6050595

US3542168
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 26 Nov 2020 09:37:10

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-2022-1614-6050596

	Yes ☐
PC Time stamp	08 SEP 2020 13:26
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3542168
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 26 Nov 2020 09:37:10

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-2022-1614-6050598

	Yes ☐
PC Time stamp	09 SEP 2020 12:08
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3542168
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 26 Nov 2020 09:37:10

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-2022-1614-6050600

US3542168
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 26 Nov 2020 09:37:10

	Yes ☐
PC Time stamp	10 SEP 2020 20:31
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

FDA-CBER-2022-1614-6050601

US3542168
Folder: Safety Call Day 8 (1)
Form: Safety Call
Data signed: (b) (4) **17 Sep 2020 04:28:58**
Generated On: 26 Nov 2020 09:37:10

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	14 SEP 2020
Please select one status for the follow-up contact	Contact Made ☐ Contact Not Made ■
Comments *If Contact Not Made, please provide Comments*	CALLED 5 TIMES IN 2 DAYS. UNABLE TO LEAVE VOICEMAIL.

FDA-CBER-2022-1614-6050602

US3542168
Folder: Safety Call Day 8 (1)
Form: Continuing
Data signed: (b) (4) **17 Sep 2020 04:28:58**
Generated On: 26 Nov 2020 09:37:10

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

FDA-CBER-2022-1614-6050603

US3542168
Folder: Safety Call Day 15 (1)
Form: Safety Call
Data signed: (b) (4) **03 Nov 2020 21:24:13**
Generated On: 26 Nov 2020 09:37:10

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

FDA-CBER-2022-1614-6050604

US3542168
Folder: Safety Call Day 15 (1)
Form: Continuing
Data signed: (b) (4) **01 Oct 2020 04:09:17**
Generated On: 26 Nov 2020 09:37:10

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

FDA-CBER-2022-1614-6050605

US3542168
Folder: Safety Call Day 22 (1)
Form: Safety Call
Data signed: (b) (4) **01 Oct 2020 04:09:17**
Generated On: 26 Nov 2020 09:37:10

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	25 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-2022-1614-6050606

US3542168
Folder: Safety Call Day 22 (1)
Form: Continuing
Data signed: (b) (4) **16 Oct 2020 04:17:01**
Generated On: 26 Nov 2020 09:37:10

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

FDA-CBER-2022-1614-6050607

US3542168
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Data signed: (b) (4) **16 Oct 2020 04:17:01**
Generated On: 26 Nov 2020 09:37:10

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	8 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	VISIT2

FDA-CBER-2022-1614-6050608

US3542168
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Data signed: (b) (4) **16 Oct 2020 04:17:01**
Generated On: 26 Nov 2020 09:37:10

Timepoint	Pre-Dose ■ Post-Dose ☐
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	8 OCT 2020
Time of assessment *(00:00-23:59)*	10:47 (24 HR)
Vital Signs Date and Time (derived)	8 OCT 2020 10:47
Temperature *(xxx.x)*	98.4 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	73 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	92 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-6050609

US3542168
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Data signed: (b) (4) **16 Oct 2020 04:17:01**
Generated On: 26 Nov 2020 09:37:10

Timepoint	Pre-Dose ☐ Post-Dose ■
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	

FDA-CBER-2022-1614-6050610

US3542168
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Data signed: (b) (4) **16 Oct 2020 04:17:01**
Generated On: 26 Nov 2020 09:37:10

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

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

FDA-CBER-2022-1614-6050611

US3542168
Folder: Visit 2 Day 29 (1)
Form: Exposure
Data signed: (b) (4) **16 Oct 2020 04:17:01**
Generated On: 26 Nov 2020 09:37:10

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?	
What was the treatment date? *(dd MMM yyyy)*	
What was the treatment time? *(00:00-23:59)*	
Treatment Date and Time (derived)	
Which arm was used to give treatment?	Left Arm ☐ Right Arm ☐
What was the frequency of the study treatment dosing?	
What was the route of administration for the study treatment?	

FDA-CBER-2022-1614-6050612

US3542168
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **16 Oct 2020 04:17:01**
Generated On: 26 Nov 2020 09:37:10

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	8 OCT 2020
Collection time *(00:00-23:59)*	11:40 (24 HR)
Collection date and time (derived)	8 OCT 2020 11:40

FDA-CBER-2022-1614-6050613

US3542168
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab
Data signed: (b) (4) **16 Oct 2020 04:17:01**
Generated On: 26 Nov 2020 09:37:10

Collection date *(dd MMM yyyy)*			8 OCT 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:15	8 OCT 2020 11:15
Nasopharyngeal Swab 2	No		

FDA-CBER-2022-1614-6050614

US3542168
Folder: Visit 2 Day 29 (1)
Form: Continuing
Data signed: (b) (4) **16 Oct 2020 04:17:01**
Generated On: 26 Nov 2020 09:37:10

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

FDA-CBER-2022-1614-6050615

US3542168
Folder: Safety Call Day 36 (1)
Form: Safety Call
Data signed: (b) (4) **21 Oct 2020 18:46:00**
Generated On: 26 Nov 2020 09:37:10

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	15 OCT 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments	
If Contact Not Made, please provide Comments	

FDA-CBER-2022-1614-6050616

US3542168
Folder: Safety Call Day 36 (1)
Form: Continuing
Data signed: (b) (4) **21 Oct 2020 18:46:00**
Generated On: 26 Nov 2020 09:37:10

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

FDA-CBER-2022-1614-6050617

US3542168
Folder: Safety Call Day 43 (1)
Form: Safety Call
Data signed: (b) (4) **30 Oct 2020 01:28:16**
Generated On: 26 Nov 2020 09:37:10

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

FDA-CBER-2022-1614-6050618

US3542168
Folder: Safety Call Day 43 (1)
Form: Continuing
Data signed: (b) (4) **30 Oct 2020 01:28:16**
Generated On: 26 Nov 2020 09:37:10

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

FDA-CBER-2022-1614-6050619

US3542168
Folder: Safety Call Day 50 (1)
Form: Safety Call
Data signed: (b) (4) **31 Oct 2020 18:33:49**
Generated On: 26 Nov 2020 09:37:10

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	29 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-2022-1614-6050620

US3542168
Folder: Safety Call Day 50 (1)
Form: Continuing
Data signed: (b) (4) **31 Oct 2020 18:33:49**
Generated On: 26 Nov 2020 09:37:10

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

FDA-CBER-2022-1614-6050621

US3542168
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Data signed: (b) (4) **20 Nov 2020 04:15:40**
Generated On: 26 Nov 2020 09:37:10

Was this visit performed?	Yes ☑ No ☐
Visit date (dd MMM yyyy)	12 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ☑
Folder OID	VISIT3

FDA-CBER-2022-1614-6050622

US3542168
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 09:37:10

Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	12 NOV 2020
Time of assessment *(00:00-23:59)*	12:56 (24 HR)
Vital Signs Date and Time (derived)	12 NOV 2020 12:56
Temperature *(xxx.x)*	98.5 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	58 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	76 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

FDA-CBER-2022-1614-6050623

US3542168
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Data signed: (b) (4) **20 Nov 2020 04:15:40**
Generated On: 26 Nov 2020 09:37:10

Was the physical examination performed?	Yes ☑ No ☐
Date of examination *(dd MMM yyyy)*	12 NOV 2020

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

FDA-CBER-2022-1614-6050624

US3542168
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **20 Nov 2020 04:15:40**
Generated On: 26 Nov 2020 09:37:10

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	12 NOV 2020
Collection time *(00:00-23:59)*	12:57 (24 HR)
Collection date and time (derived)	12 NOV 2020 12:57

FDA-CBER-2022-1614-6050625

US3542168
Folder: Visit 3 Day 57 (1)
Form: Continuing
Data signed: (b) (4) **20 Nov 2020 04:15:40**
Generated On: 26 Nov 2020 09:37:10

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

FDA-CBER-2022-1614-6050626

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-2022-1614-6050627

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2020 00:01
Patient Cloud Close Date & Time	08 NOV 2020 23:59

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-6050629

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2020 00:01
Patient Cloud Close Date & Time	15 NOV 2020 23:59

FDA-CBER-2022-1614-6050630

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-6050631

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2020 00:01
Patient Cloud Close Date & Time	22 NOV 2020 23:59

FDA-CBER-2022-1614-6050632

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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-2022-1614-6050633

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2020 00:01
Patient Cloud Close Date & Time	06 DEC 2020 23:59

FDA-CBER-2022-1614-6050634

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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-2022-1614-6050635

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2020 00:01
Patient Cloud Close Date & Time	13 DEC 2020 23:59

FDA-CBER-2022-1614-6050636

TIMEPOINT	DAY 106
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 DEC 2020 00:01
Patient Cloud Close Date & Time	20 DEC 2020 23:59

FDA-CBER-2022-1614-6050638

TIMEPOINT	DAY 113
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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-2022-1614-6050639

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2020 00:01
Patient Cloud Close Date & Time	27 DEC 2020 23:59

FDA-CBER-2022-1614-6050640

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10

TIMEPOINT	DAY 126
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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-2022-1614-6050641

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10

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

FDA-CBER-2022-1614-6050642

TIMEPOINT	DAY 133
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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-2022-1614-6050643

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10

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

FDA-CBER-2022-1614-6050644

TIMEPOINT	DAY 140
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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-2022-1614-6050645

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

TIMEPOINT	DAY 154
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 ☐

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10

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

FDA-CBER-2022-1614-6050648

TIMEPOINT	DAY 161
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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-2022-1614-6050649

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10

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

FDA-CBER-2022-1614-6050650

TIMEPOINT	DAY 168
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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-2022-1614-6050651

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

FDA-CBER-2022-1614-6050652

TIMEPOINT	DAY 182
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

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

FDA-CBER-2022-1614-6050654

TIMEPOINT	DAY 189
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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-2022-1614-6050655

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10

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

FDA-CBER-2022-1614-6050656

TIMEPOINT	DAY 196
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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-2022-1614-6050657

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

FDA-CBER-2022-1614-6050658

TIMEPOINT	DAY 203
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 MAR 2021 00:01
Patient Cloud Close Date & Time	27 MAR 2021 23:59

FDA-CBER-2022-1614-6050660

TIMEPOINT	DAY 216
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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-2022-1614-6050661

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

FDA-CBER-2022-1614-6050662

TIMEPOINT	DAY 223
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 APR 2021 00:01
Patient Cloud Close Date & Time	16 APR 2021 23:59

FDA-CBER-2022-1614-6050664

TIMEPOINT	DAY 230
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 ☐

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10

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

FDA-CBER-2022-1614-6050666

TIMEPOINT	DAY 246
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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-2022-1614-6050667

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

TIMEPOINT	DAY 253
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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-2022-1614-6050669

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

TIMEPOINT	DAY 260
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 ☐

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10

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

FDA-CBER-2022-1614-6050672

TIMEPOINT	DAY 276
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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-2022-1614-6050673

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

TIMEPOINT	DAY 283
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 ☐

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10

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

FDA-CBER-2022-1614-6050676

TIMEPOINT	DAY 290
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 ☐

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10

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

FDA-CBER-2022-1614-6050678

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 ☐

FDA-CBER-2022-1614-6050679

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10

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

FDA-CBER-2022-1614-6050680

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 ☐

FDA-CBER-2022-1614-6050681

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10

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

FDA-CBER-2022-1614-6050682

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 ☐

FDA-CBER-2022-1614-6050683

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10

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

FDA-CBER-2022-1614-6050684

TIMEPOINT	DAY 336
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 ☐

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2021 00:01
Patient Cloud Close Date & Time	07 AUG 2021 23:59

FDA-CBER-2022-1614-6050686

TIMEPOINT	DAY 343
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 ☐

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10

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

FDA-CBER-2022-1614-6050688

TIMEPOINT	DAY 350
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 AUG 2021 00:01
Patient Cloud Close Date & Time	21 AUG 2021 23:59

FDA-CBER-2022-1614-6050690

TIMEPOINT	DAY 366
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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-2022-1614-6050691

Please contact your study clinic immediately. Click below to confirm that you have read this 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

FDA-CBER-2022-1614-6050692

TIMEPOINT	DAY 373
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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-2022-1614-6050693

Please contact your study clinic immediately. Click below to confirm that you have read this 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 380
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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-2022-1614-6050695

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10

Please contact your study clinic immediately. Click below to confirm that you have read this 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

FDA-CBER-2022-1614-6050696

TIMEPOINT	DAY 387
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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-2022-1614-6050697

Please contact your study clinic immediately. Click below to confirm that you have read this 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

FDA-CBER-2022-1614-6050698

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10

TIMEPOINT	DAY 401
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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-2022-1614-6050699

Please contact your study clinic immediately. Click below to confirm that you have read this 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

TIMEPOINT	DAY 408
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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-2022-1614-6050701

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10

Please contact your study clinic immediately. Click below to confirm that you have read this 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-2022-1614-6050702

TIMEPOINT	DAY 415
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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-2022-1614-6050703

Please contact your study clinic immediately. Click below to confirm that you have read this 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-2022-1614-6050704

TIMEPOINT	DAY 431
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

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

FDA-CBER-2022-1614-6050706

TIMEPOINT	DAY 438
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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-2022-1614-6050707

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10

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

FDA-CBER-2022-1614-6050708

TIMEPOINT	DAY 445
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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-2022-1614-6050709

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10

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

FDA-CBER-2022-1614-6050710

TIMEPOINT	DAY 461
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

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

FDA-CBER-2022-1614-6050712

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10

TIMEPOINT	DAY 468
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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-2022-1614-6050713

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

TIMEPOINT	DAY 475
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

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

FDA-CBER-2022-1614-6050716

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10

TIMEPOINT	DAY 491
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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-2022-1614-6050717

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

TIMEPOINT	DAY 498
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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-2022-1614-6050719

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10

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

FDA-CBER-2022-1614-6050720

TIMEPOINT	DAY 505
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 ☐

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10

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

FDA-CBER-2022-1614-6050722

TIMEPOINT	DAY 521
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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	04 FEB 2022 00:01
Patient Cloud Close Date & Time	08 FEB 2022 23:59

TIMEPOINT	DAY 528
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 2022 00:01
Patient Cloud Close Date & Time	15 FEB 2022 23:59

TIMEPOINT	DAY 535
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	18 FEB 2022 00:01
Patient Cloud Close Date & Time	22 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	06 MAR 2022 00:01
Patient Cloud Close Date & Time	10 MAR 2022 23:59

FDA-CBER-2022-1614-6050730

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

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

FDA-CBER-2022-1614-6050732

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	20 MAR 2022 00:01
Patient Cloud Close Date & Time	24 MAR 2022 23:59

FDA-CBER-2022-1614-6050734

US3542168
Folder: Safety Follow Up Diary (1)
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Generated On: 26 Nov 2020 09:37:10

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 ☐

FDA-CBER-2022-1614-6050735

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

FDA-CBER-2022-1614-6050736

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

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

FDA-CBER-2022-1614-6050738

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	10 APR 2022 00:01
Patient Cloud Close Date & Time	14 APR 2022 23:59

FDA-CBER-2022-1614-6050740

TIMEPOINT	DAY 595
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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-2022-1614-6050741

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

FDA-CBER-2022-1614-6050742

TIMEPOINT	DAY 611
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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-2022-1614-6050743

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

FDA-CBER-2022-1614-6050744

TIMEPOINT	DAY 618
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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-2022-1614-6050745

Please contact your study clinic immediately. Click below to confirm that you have read this 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

FDA-CBER-2022-1614-6050746

TIMEPOINT	DAY 625
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 ☐

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10

Please contact your study clinic immediately. Click below to confirm that you have read this 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

FDA-CBER-2022-1614-6050748

TIMEPOINT	DAY 641
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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-2022-1614-6050749

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

TIMEPOINT	DAY 648
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 JUN 2022 00:01
Patient Cloud Close Date & Time	15 JUN 2022 23:59

FDA-CBER-2022-1614-6050752

TIMEPOINT	DAY 655
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 ☐

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10

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

FDA-CBER-2022-1614-6050754

TIMEPOINT	DAY 671
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 ☐

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10

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

FDA-CBER-2022-1614-6050756

TIMEPOINT	DAY 678
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 ☐

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10

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

FDA-CBER-2022-1614-6050758

TIMEPOINT	DAY 685
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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-2022-1614-6050759

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

FDA-CBER-2022-1614-6050760

TIMEPOINT	DAY 701
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 ☐

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10

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

FDA-CBER-2022-1614-6050762

TIMEPOINT	DAY 708
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 AUG 2022 00:01
Patient Cloud Close Date & Time	14 AUG 2022 23:59

FDA-CBER-2022-1614-6050764

TIMEPOINT	DAY 715
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 AUG 2022 00:01
Patient Cloud Close Date & Time	21 AUG 2022 23:59

FDA-CBER-2022-1614-6050766

TIMEPOINT	DAY 731
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

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

FDA-CBER-2022-1614-6050768

TIMEPOINT	DAY 738
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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	09 SEP 2022 00:01
Patient Cloud Close Date & Time	13 SEP 2022 23:59

FDA-CBER-2022-1614-6050770

TIMEPOINT	DAY 745
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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-2022-1614-6050771

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

FDA-CBER-2022-1614-6050772

TIMEPOINT	DAY 752
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 SEP 2022 00:01
Patient Cloud Close Date & Time	27 SEP 2022 23:59

US3542168
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 26 Nov 2020 09:37:10

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-2022-1614-6050775

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

FDA-CBER-2022-1614-6050776

US3542168
Folder: Covid-19 Assessment (1)
Form: COVID-19 Contact
Generated On: 26 Nov 2020 09:37:10

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-2022-1614-6050777

Generate Next COVID-19 Assessment	Yes ☐ No ☐

FDA-CBER-2022-1614-6050778

US3542168
Folder: Adverse Events
Form: Adverse Events Summary
Data signed: (b) (4) **18 Sep 2020 17:11:07**
Generated On: 26 Nov 2020 09:37:10

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

If Yes, enter details on the Adverse Events form.

FDA-CBER-2022-1614-6050779

US3542168
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:37:10

AEID	USA-US084-2020-MRNA-1273-P30 1000001
Adverse event	ANXIETY EXACERBATION
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)*	10 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)*	18 SEP 2020
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ■
Is the adverse event serious?	Yes ■ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date *(dd MMM yyyy)*	10 SEP 2020
Hospital Discharge Date *(dd MMM yyyy)*	18 SEP 2020
Admitted to ICU?	Yes ☐ No ■ Unknown ☐
Number of Days in ICU	

FDA-CBER-2022-1614-6050780

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ■ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ■ Related ☐ Not Applicable ☐
Action taken with investigational product	None ■ Dose Delayed ☐ Investigational Product Withdrawn ☐ Not Applicable ☐
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ■ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	

Narrative

FDA-CBER-2022-1614-6050781

PARTICIPANT REPORTED TO SITE ON 18SEP2020 THAT HE HAD JUST BEEN DISCHARGED FROM HOSPITAL THIS DAY AFTER HAVING BEEN ADMITTED TO THE PSYCHIATRIC SERVICE ON 10SEP2020 DUE TO WORSENED ANXIETY. HE STATES THAT HE HAS PRE-EXISTING DIAGNOSES OF ANXIETY AND DEPRESSION FOR THE PAST 20 YEARS THAT WERE NOT RELATED TO THE STUDY TEAM AT SCREENING/ENROLLMENT. HE HAS BEEN TREATED FOR THE PAST YEAR WITH REMERON 15MG/DAY (ALSO NOT REPORTED TO THE STUDY TEAM AT SCREENING/ENROLLMENT).

ACCORDING TO THE PARTICIPANT, HIS GIRLFRIEND WAS RECENTLY DIAGNOSED WITH CERVICAL CANCER, WHICH LED TO WORSENED SYMPTOMS OF ANXIETY ON 10SEP2020, PROMPTING HIM TO GO TO THE EMERGENCY DEPARTMENT OF A LOCAL COMMUNITY HOSPITAL (NOT AT THE STUDY SITE). HE WAS ADMITTED TO THE PSYCHIATRY SERVICE FOR MEDICATION ADJUSTMENT. HIS DOSE OF REMERON WAS

FDA-CBER-2022-1614-6050782

	INCREASED TO 30MG/DAY ACCORDING TO THE PARTICIPANT. DURING HIS IN-PATIENT STAY HIS SYMPTOMS OF ANXIETY IMPROVED AND HE WAS THEREFORE DISCHARGED HOME THE MORNING OF 18SEP2020. HE WILL FOLLOW-UP WITH HIS REGULAR PSYCHIATRIST. HE DENIES HAVING ANY POTENTIAL COVID-19 SYMPTOMS: NO FEVER, CHILLS, DYSPNEA, COUGH, LOSS OF TASTE OR SMELL, RHINORRHEA, NASAL CONGESTION, SORE THROAT, MYALGIAS, ARTHRALGIAS, HEADACHE, FATIGUE, NAUSEA, OR DIARRHEA. NO RECENT TRAVEL OR SICK CONTACTS. HE RECEIVED HIS FIRST DOSE OF VACCINE/PLACEBO ON 04SEPT2020.
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

US3542168
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 26 Nov 2020 09:37:10

AEID	USA-US084-2020-MRNA-1273-P30 1000001
Adverse event	ANXIETY EXACERBATION
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)*	19 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)*	23 SEP 2020
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ■ Grade 4 ☐
Is the adverse event serious?	Yes ■ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date *(dd MMM yyyy)*	19 SEP 2020
Hospital Discharge Date *(dd MMM yyyy)*	23 SEP 2020
Admitted to ICU?	Yes ☐ No ■ Unknown ☐
Number of Days in ICU	

FDA-CBER-2022-1614-6050784

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

FDA-CBER-2022-1614-6050785

	PARTICIPANT CALLED STUDY TEAM ON 24SEP2020 TO REPORT THAT HE HAD BEEN RE-ADMITTED TO THE PSYCHIATRIC WARD OF A LOCAL HOSPITAL ON 19SEP2020 DUE TO RECURRENCE OF SYMPTOMS OF SEVERE ANXIETY. WHILE IN HOSPITAL HE WAS DIAGNOSED WITH BORDERLINE PERSONALITY DISORDER AND STARTED ON BOTH LITHIUM AND MIRTAZIPINE, WITH IMPROVEMENT OF SYMPTOMS. HE WAS DISCHARGED ON 23SEP2020 WITH FOLLOW-UP PLANNED WITH OUTPATIENT PSYCHIATRY.
Serious Adverse Event Derived (CSA Programming Field Ony)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

FDA-CBER-2022-1614-6050786

US3542168
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 26 Nov 2020 09:37:10

AEID	USA-US084-2020-MRNA-1273-P30 1000001
Adverse event	DEPRESSION EXACERBATION
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)*	19 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)*	23 SEP 2020
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ■ Grade 4 ☐
Is the adverse event serious?	Yes ■ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date *(dd MMM yyyy)*	19 SEP 2020
Hospital Discharge Date *(dd MMM yyyy)*	23 SEP 2020
Admitted to ICU?	Yes ☐ No ■ Unknown ☐
Number of Days in ICU	

FDA-CBER-2022-1614-6050787

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

FDA-CBER-2022-1614-6050788

	PARTICIPANT WENT TO EMERGENCY DEPARTMENT TO BE TREATED FOR LOWER LEG PAIN, THOUGHT TO BE ATTRIBUTED TO SICKLE CELL DISEASE. HE WAS THEN ADMITTED TO THE PSYCH DEPARTMENT FOR EXACERBATION OF CHRONIC ANXIETY AND DEPRESSION. HE WAS DIAGNOSED WITH PTSD AND BORDERLINE PERSONALITY DISORDER AND GIVEN MEDICATION FOR TREATMENT.
Serious Adverse Event Derived (CSA Programming Field Ony)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

FDA-CBER-2022-1614-6050789

US3542168
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 26 Nov 2020 09:37:10

AEID	
Adverse event	LOWER LEG PAIN
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)*	18 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)*	19 SEP 2020
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ■ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ■
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	
Persistent or significant disability or incapacity	False

FDA-CBER-2022-1614-6050790

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)	

FDA-CBER-2022-1614-6050791

US3542168
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 26 Nov 2020 09:37:10

AEID	
Adverse event	RHINORRHEA
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)*	21 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)*	23 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

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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)	

FDA-CBER-2022-1614-6050793

US3542168
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 26 Nov 2020 09:37:10

AEID	
Adverse event	HEADACHE
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)*	21 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)*	23 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

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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)	0
Admitted to ICU Derived (CSA Programming Field Only)	

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US3542168
Folder: Adverse Events
Form: Adverse Events (7)
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AEID	
Adverse event	RIGHT TRAPEZIUS STRAIN
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)*	10 NOV 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ■ No ☐
If not Ongoing, end date *(dd MMM yyyy)*	
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

FDA-CBER-2022-1614-6050796

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)	0
Admitted to ICU Derived (CSA Programming Field Only)	

FDA-CBER-2022-1614-6050797

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination Summary
Data signed: (b) (4) **24 Sep 2020 11:50:06**
Generated On: 26 Nov 2020 09:37:10

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

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

FDA-CBER-2022-1614-6050798

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Data signed: (b) (4) **20 Nov 2020 04:15:39**
Generated On: 26 Nov 2020 09:37:10

Name of Medication	LISINOPRIL
Prophylaxis	Yes ☐ No ■
Indication	HYPERTENSION
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-2022-1614-6050799

	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 2018
Start date completely unknown	False
Ongoing?	Yes ■
	No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

Name of Medication	REMERON
Prophylaxis	Yes ☐ No ■
Indication	GENERALIZED ANXIETY DISORDER
Dose per administration	15
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 ☐

FDA-CBER-2022-1614-6050801

	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 2019
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	10 SEP 2020
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

Name of Medication	REMERON
Prophylaxis	Yes ☐ No ■
Indication	GENERALIZED ANXIETY DISORDER
Dose per administration	30
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ■ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐

	Intraocular ☐
	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	10 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)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Data signed: (b) (4) **20 Nov 2020 04:15:39**
Generated On: 26 Nov 2020 09:37:10

Name of Medication	MIRTAZAPINE
Prophylaxis	Yes ☐ No ■
Indication	DEPRESSION
Dose per administration	3
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ■ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

FDA-CBER-2022-1614-6050805

	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)*	20 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)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

Name of Medication	LITHIUM
Prophylaxis	Yes ☐ No ■
Indication	DEPRESSION AND ANXIETY
Dose per administration	300
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-2022-1614-6050807

	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)*	20 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)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

Name of Medication	PRAZOSIN
Prophylaxis	Yes ☐ No ■
Indication	PTSD
Dose per administration	3
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ■ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

	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)*	20 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)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Data signed: (b) (4) **20 Nov 2020 04:15:39**
Generated On: 26 Nov 2020 09:37:10

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

FDA-CBER-2022-1614-6050811

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

Name of Medication	MORPHINE
Prophylaxis	Yes ☐ No ■
Indication	LOWER LEG PAIN
Dose per administration	4
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ■ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ■
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	19 SEP 2020
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	19 SEP 2020
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☐

Name of Medication	DILAUDID
Prophylaxis	Yes ☐ No ■
Indication	LOWER LEG PAIN
Dose per administration	1
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ■
If frequency is Other, specify	TWICE
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

FDA-CBER-2022-1614-6050815

	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)*	19 SEP 2020
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	19 SEP 2020
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☐

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Data signed: (b) (4) **20 Nov 2020 04:15:39**
Generated On: 26 Nov 2020 09:37:10

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

FDA-CBER-2022-1614-6050817

	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)*	19 SEP 2020
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	19 SEP 2020
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☐

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

FDA-CBER-2022-1614-6050819

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

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Data signed: (b) (4) **20 Nov 2020 04:15:39**
Generated On: 26 Nov 2020 09:37:10

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

FDA-CBER-2022-1614-6050821

	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)*	10 NOV 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 ■

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Data signed: (b) (4) **20 Nov 2020 04:15:39**
Generated On: 26 Nov 2020 09:37:10

Name of Medication	BC POWDER (ASPIRIN)
Prophylaxis	Yes ☐
	No ■
Indication	HEADACHE
Dose per administration	1
Dose unit	mg ☐
	ug ☐
	mL ☐
	g ☐
	IU ☐
	tablet ☐
	capsule ☐
	puff ☐
	Other ■
If dose unit is Other, specify	PACKET
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-2022-1614-6050823

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

US3542168
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures Summary
Generated On: 26 Nov 2020 09:37:10

Were any concomitant procedures performed?	Yes ☐
	No ☐

If yes, please complete Concomitant Procedures form.

FDA-CBER-2022-1614-6050825

US3542168
Folder: End of Study (1)
Form: Dosing Discontinuation
Data signed: (b) (4) **21 Oct 2020 18:46:00**
Generated On: 26 Nov 2020 09:37:10

Date of dosing discontinuation (dd MMM yyyy)	08 OCT 2020
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	PHYSICIAN WITHHELD DOSE DUE TO HOSPITAL ADMISSIONS FOR PSYCHIATRIC REASONS

FDA-CBER-2022-1614-6050826

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

FDA-CBER-2022-1614-6050827

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 09:37:10

SAEID	USA-US084-2020-MRNA-1273-P301000001
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	DC
Site Address: Postal Code	20037
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5

FDA-CBER-2022-1614-6050828

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form (1)
Generated On: 26 Nov 2020 09:37:10

SAEID	USA-US084-2020-MRNA-1273-P301000001
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	DC
Site Address: Postal Code	20037
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	20/SEP/2020 13:53
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

FDA-CBER-2022-1614-6050829

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form (2)
Generated On: 26 Nov 2020 09:37:10

SAEID	USA-US084-2020-MRNA-1273-P301000001
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	DC
Site Address: Postal Code	20037
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	28/SEP/2020 10:01
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

FDA-CBER-2022-1614-6050830

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form (3)
Generated On: 26 Nov 2020 09:37:10

SAEID	USA-US084-2020-MRNA-1273-P301000001
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	DC
Site Address: Postal Code	20037
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	30/SEP/2020 17:33
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

FDA-CBER-2022-1614-6050831

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form (4)
Generated On: 26 Nov 2020 09:37:10

SAEID	USA-US084-2020-MRNA-1273-P301000001
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	DC
Site Address: Postal Code	20037
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	28/OCT/2020 14:06
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-2022-1614-6050832

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form (5)
Generated On: 26 Nov 2020 09:37:10

SAEID	USA-US084-2020-MRNA-1273-P301000001
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	DC
Site Address: Postal Code	20037
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	23/NOV/2020 09:38
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-2022-1614-6050833

Audit

US3542168 (Prod: George Washington University)

US3542168
Form: Participant Creation
Generated On: 26 Nov 2020 09:37:10
Participant ID

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:50:51
User entered 'US3542168'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 19:34:43

FDA-CBER-2022-1614-6050835

US3542168
Folder: Screening
Form: Visit Date
Generated On: 26 Nov 2020 09:37:10
Was this visit performed?

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:50:51
User entered 'Yes (Y)'	Elissa Malkin (b) (4) (b) (4)	04 Sep 2020 19:49:00

FDA-CBER-2022-1614-6050836

US3542168
Folder: Screening
Form: Visit Date
Generated On: 26 Nov 2020 09:37:10
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:50:51
User entered '04 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 19:34:44

FDA-CBER-2022-1614-6050837

US3542168
Folder: Screening
Form: Visit Date
Generated On: 26 Nov 2020 09:37:10
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:50:51
User entered 'Clinic (Clinic)'	Elissa Malkin (b) (4) (b) (4)	04 Sep 2020 19:49:00

FDA-CBER-2022-1614-6050838

US3542168
Folder: Screening
Form: Visit Date
Generated On: 26 Nov 2020 09:37:10
Folder OID

Audit	User	Time (GMT)
User entered 'SCRN'	System	04 Sep 2020 19:49:00

FDA-CBER-2022-1614-6050839

US3542168
Folder: Screening
Form: Demographics
Generated On: 26 Nov 2020 09:37:10
Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per CDM: Kindly complete all the forms for this Visit.' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 06:34:44
Query 'Per CDM: Kindly complete all the forms for this Visit.' answered with 'Forms completed' (Site from DM).	Hannah Yellin (b) (4) (b) (4)	22 Sep 2020 18:02:45
User opened query 'Per CDM: Kindly complete all the forms for this Visit.' (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 11:47:10
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:50:51
User entered (b) (6) 1966'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 19:34:46

FDA-CBER-2022-1614-6050840

US3542168
Folder: Screening
Form: Demographics
Generated On: 26 Nov 2020 09:37:10
Age

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered '54'	Hannah Yellin (b) (4) (b) (4)	22 Sep 2020 18:01:49

FDA-CBER-2022-1614-6050841

US3542168
Folder: Screening
Form: Demographics
Generated On: 26 Nov 2020 09:37:10
Age Units

Audit	User	Time (GMT)
User entered 'YEARS'	System	22 Sep 2020 18:01:49

FDA-CBER-2022-1614-6050842

US3542168
Folder: Screening
Form: Demographics
Generated On: 26 Nov 2020 09:37:10
Age (Derived)

Audit	User	Time (GMT)
User entered '54'	System	04 Sep 2020 19:49:41

FDA-CBER-2022-1614-6050843

US3542168
Folder: Screening
Form: Demographics
Generated On: 26 Nov 2020 09:37:10
Sex

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered 'Male (M)'	Hannah Yellin (b) (4) (b) (4)	22 Sep 2020 18:01:49

FDA-CBER-2022-1614-6050844

US3542168
Folder: Screening
Form: Demographics
Generated On: 26 Nov 2020 09:37:10
Ethnicity

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Hannah Yellin (b) (4) (b) (4)	22 Sep 2020 18:01:49

FDA-CBER-2022-1614-6050845

US3542168
Folder: Screening
Form: Demographics
Generated On: 26 Nov 2020 09:37:10
White

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered '0'	Hannah Yellin (b) (4) (b) (4)	22 Sep 2020 18:01:49

FDA-CBER-2022-1614-6050846

US3542168
Folder: Screening
Form: Demographics
Generated On: 26 Nov 2020 09:37:10
Black

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered '1'	Hannah Yellin (b) (4) (b) (4)	22 Sep 2020 18:01:49

FDA-CBER-2022-1614-6050847

US3542168
Folder: Screening
Form: Demographics
Generated On: 26 Nov 2020 09:37:10
Asian

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered '0'	Hannah Yellin (b) (4) (b) (4)	22 Sep 2020 18:01:49

FDA-CBER-2022-1614-6050848

US3542168
Folder: Screening
Form: Demographics
Generated On: 26 Nov 2020 09:37:10
American Indian or Alaska Native

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered '0'	Hannah Yellin (b) (4) (b) (4)	22 Sep 2020 18:01:49

FDA-CBER-2022-1614-6050849

US3542168
Folder: Screening
Form: Demographics
Generated On: 26 Nov 2020 09:37:10
Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered '0'	Hannah Yellin (b) (4) (b) (4)	22 Sep 2020 18:01:49

FDA-CBER-2022-1614-6050850

US3542168
Folder: Screening
Form: Demographics
Generated On: 26 Nov 2020 09:37:10
Other

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered '0'	Hannah Yellin (b) (4) (b) (4)	22 Sep 2020 18:01:49

FDA-CBER-2022-1614-6050851

US3542168
Folder: Screening
Form: Demographics
Generated On: 26 Nov 2020 09:37:10
If race is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered empty.	Hannah Yellin (b) (4) (b) (4)	22 Sep 2020 18:01:49

FDA-CBER-2022-1614-6050852

US3542168
Folder: Screening
Form: Demographics
Generated On: 26 Nov 2020 09:37:10
Unknown

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered '0'	Hannah Yellin (b) (4) (b) (4)	22 Sep 2020 18:01:49

FDA-CBER-2022-1614-6050853

US3542168
Folder: Screening
Form: Demographics
Generated On: 26 Nov 2020 09:37:10
Not reported

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered '0'	Hannah Yellin (b) (4) (b) (4)	22 Sep 2020 18:01:49

FDA-CBER-2022-1614-6050854

US3542168
Folder: Screening
Form: Enrollment
Generated On: 26 Nov 2020 09:37:10
Date of Informed Consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:50:51
User entered '4 Sep 2020'	Elissa Malkin (b) (4) (b) (4)	04 Sep 2020 19:49:41

FDA-CBER-2022-1614-6050855

US3542168
Folder: Screening
Form: Enrollment
Generated On: 26 Nov 2020 09:37:10
Month and Year of Informed Consent (derived)

Audit	User	Time (GMT)
User entered 'Sep 2020'	System	04 Sep 2020 19:49:41

FDA-CBER-2022-1614-6050856

US3542168
Folder: Screening
Form: Enrollment
Generated On: 26 Nov 2020 09:37:10
Year of Informed Consent (derived)

Audit	User	Time (GMT)
User entered '2020'	System	04 Sep 2020 19:49:41

FDA-CBER-2022-1614-6050857

US3542168
Folder: Screening
Form: Enrollment
Generated On: 26 Nov 2020 09:37:10
Protocol Version

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:50:51
User entered 'Amendment 3 (3)'	Elissa Malkin (b) (4) (b) (4)	04 Sep 2020 19:49:41

FDA-CBER-2022-1614-6050858

US3542168
Folder: Screening
Form: Enrollment
Generated On: 26 Nov 2020 09:37:10
Was participant enrolled in the study?

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:50:51
User entered 'Yes (Y)'	Elissa Malkin (b) (4) (b) (4)	04 Sep 2020 19:49:41

FDA-CBER-2022-1614-6050859

US3542168
Folder: Screening
Form: Enrollment
Generated On: 26 Nov 2020 09:37:10
If No, indicate reason for screen fail

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:50:51
User entered empty.	Elissa Malkin (b) (4) (b) (4)	04 Sep 2020 19:49:41

FDA-CBER-2022-1614-6050860

US3542168
Folder: Screening
Form: Enrollment
Generated On: 26 Nov 2020 09:37:10
If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:50:51
User entered empty.	Elissa Malkin (b) (4) (b) (4)	04 Sep 2020 19:49:41

FDA-CBER-2022-1614-6050861

US3542168
Folder: Screening
Form: Enrollment
Generated On: 26 Nov 2020 09:37:10
Was this participant screened previously?

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:50:51
User entered 'No (N)'	Elissa Malkin (b) (4) (b) (4)	04 Sep 2020 19:49:41

FDA-CBER-2022-1614-6050862

US3542168
Folder: Screening
Form: Enrollment
Generated On: 26 Nov 2020 09:37:10
If Yes, previous participant number

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:50:51
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 19:34:44

FDA-CBER-2022-1614-6050863

US3542168
Folder: Screening
Form: Enrollment
Generated On: 26 Nov 2020 09:37:10
Enrollment Trigger

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 19:49:54

FDA-CBER-2022-1614-6050864

US3542168
Folder: Screening
Form: Inclusion/Exclusion Criteria Summary
Generated On: 26 Nov 2020 09:37:10
Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:50:51
User entered 'Yes (Y)'	Elissa Malkin (b) (4) (b) (4)	04 Sep 2020 19:49:54

FDA-CBER-2022-1614-6050865

US3542168
Folder: Screening
Form: Medical History Summary
Generated On: 26 Nov 2020 09:37:10
Were any significant conditions reported?

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered 'Yes (Y)'	Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:50:31

FDA-CBER-2022-1614-6050866

US3542168
Folder: Screening
Form: Medical History (1)
Generated On: 26 Nov 2020 09:37:10
Condition

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Sep 2020 18:52:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Sep 2020 18:52:54
Data point term sent to Coder	System	21 Sep 2020 18:51:41
User entered 'hypertension'	Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:50:45

FDA-CBER-2022-1614-6050867

US3542168
Folder: Screening
Form: Medical History (1)
Generated On: 26 Nov 2020 09:37:10
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered 'un UNK 2018'	Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:50:45

FDA-CBER-2022-1614-6050868

US3542168
Folder: Screening
Form: Medical History (1)
Generated On: 26 Nov 2020 09:37:10
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered '0'	Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:50:45

FDA-CBER-2022-1614-6050869

US3542168
Folder: Screening
Form: Medical History (1)
Generated On: 26 Nov 2020 09:37:10
Condition ongoing at study entry

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered 'Yes (Y)'	Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:50:45

FDA-CBER-2022-1614-6050870

US3542168
Folder: Screening
Form: Medical History (1)
Generated On: 26 Nov 2020 09:37:10
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered empty.	Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:50:45

FDA-CBER-2022-1614-6050871

US3542168
Folder: Screening
Form: Medical History (1)
Generated On: 26 Nov 2020 09:37:10
Stop date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered '0'	Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:50:45

FDA-CBER-2022-1614-6050872

US3542168
Folder: Screening
Form: Medical History (1)
Generated On: 26 Nov 2020 09:37:10
Start Month and Year (derived)

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	21 Sep 2020 18:50:45

FDA-CBER-2022-1614-6050873

US3542168
Folder: Screening
Form: Medical History (1)
Generated On: 26 Nov 2020 09:37:10
Start Year (derived)

Audit	User	Time (GMT)
User entered '2018'	System	21 Sep 2020 18:50:45

FDA-CBER-2022-1614-6050874

US3542168
Folder: Screening
Form: Medical History (1)
Generated On: 26 Nov 2020 09:37:10
Stop Month and Year (derived)

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 18:50:45

FDA-CBER-2022-1614-6050875

US3542168
Folder: Screening
Form: Medical History (1)
Generated On: 26 Nov 2020 09:37:10
Stop Year (derived)

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 18:50:45

FDA-CBER-2022-1614-6050876

US3542168
Folder: Screening
Form: Medical History (2)
Generated On: 26 Nov 2020 09:37:10
Condition

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Skin and subcutaneous tissue therapeutic procedures, HLT: Skin grafts, PT: Skin graft, LLT: Skin graft - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Oct 2020 06:31:19
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Oct 2020 06:31:19
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
Data point term sent to Coder	System	21 Sep 2020 18:51:41
User entered 'skin grafts for burn'	Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:50:59

FDA-CBER-2022-1614-6050877

US3542168
Folder: Screening
Form: Medical History (2)
Generated On: 26 Nov 2020 09:37:10
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered 'un UNK 1992'	Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:50:59

FDA-CBER-2022-1614-6050878

US3542168
Folder: Screening
Form: Medical History (2)
Generated On: 26 Nov 2020 09:37:10
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered '0'	Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:50:59

FDA-CBER-2022-1614-6050879

US3542168
Folder: Screening
Form: Medical History (2)
Generated On: 26 Nov 2020 09:37:10
Condition ongoing at study entry

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered 'No (N)'	Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:50:59

FDA-CBER-2022-1614-6050880

US3542168
Folder: Screening
Form: Medical History (2)
Generated On: 26 Nov 2020 09:37:10
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered 'un UNK 1992'	Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:50:59

FDA-CBER-2022-1614-6050881

US3542168
Folder: Screening
Form: Medical History (2)
Generated On: 26 Nov 2020 09:37:10
Stop date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered '0'	Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:50:59

FDA-CBER-2022-1614-6050882

US3542168
Folder: Screening
Form: Medical History (2)
Generated On: 26 Nov 2020 09:37:10
Start Month and Year (derived)

Audit	User	Time (GMT)
User entered 'Jan 1992'	System	21 Sep 2020 18:50:59

FDA-CBER-2022-1614-6050883

US3542168
Folder: Screening
Form: Medical History (2)
Generated On: 26 Nov 2020 09:37:10
Start Year (derived)

Audit	User	Time (GMT)
User entered '1992'	System	21 Sep 2020 18:50:59

FDA-CBER-2022-1614-6050884

US3542168
Folder: Screening
Form: Medical History (2)
Generated On: 26 Nov 2020 09:37:10
Stop Month and Year (derived)

Audit	User	Time (GMT)
User entered 'Jan 1992'	System	21 Sep 2020 18:50:59

FDA-CBER-2022-1614-6050885

US3542168
Folder: Screening
Form: Medical History (2)
Generated On: 26 Nov 2020 09:37:10
Stop Year (derived)

Audit	User	Time (GMT)
User entered '1992'	System	21 Sep 2020 18:50:59

FDA-CBER-2022-1614-6050886

US3542168
Folder: Screening
Form: Medical History (3)
Generated On: 26 Nov 2020 09:37:10
Condition

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety disorders NEC, PT: Generalised anxiety disorder, LLT: Generalized anxiety disorder - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Sep 2020 18:52:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Sep 2020 18:52:55
Data point term sent to Coder	System	21 Sep 2020 18:51:39
User entered 'generalized anxiety disorder'	Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:51:06

FDA-CBER-2022-1614-6050887

US3542168
Folder: Screening
Form: Medical History (3)
Generated On: 26 Nov 2020 09:37:10
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered 'un UNK 2000'	Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:51:06

FDA-CBER-2022-1614-6050888

US3542168
Folder: Screening
Form: Medical History (3)
Generated On: 26 Nov 2020 09:37:10
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered '0'	Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:51:06

FDA-CBER-2022-1614-6050889

US3542168
Folder: Screening
Form: Medical History (3)
Generated On: 26 Nov 2020 09:37:10
Condition ongoing at study entry

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered 'Yes (Y)'	Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:51:06

FDA-CBER-2022-1614-6050890

US3542168
Folder: Screening
Form: Medical History (3)
Generated On: 26 Nov 2020 09:37:10
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered empty.	Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:51:06

FDA-CBER-2022-1614-6050891

US3542168
Folder: Screening
Form: Medical History (3)
Generated On: 26 Nov 2020 09:37:10
Stop date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered '0'	Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:51:06

FDA-CBER-2022-1614-6050892

US3542168
Folder: Screening
Form: Medical History (3)
Generated On: 26 Nov 2020 09:37:10
Start Month and Year (derived)

Audit	User	Time (GMT)
User entered 'Jan 2000'	System	21 Sep 2020 18:51:06

FDA-CBER-2022-1614-6050893

US3542168
Folder: Screening
Form: Medical History (3)
Generated On: 26 Nov 2020 09:37:10
Start Year (derived)

Audit	User	Time (GMT)
User entered '2000'	System	21 Sep 2020 18:51:06

FDA-CBER-2022-1614-6050894

US3542168
Folder: Screening
Form: Medical History (3)
Generated On: 26 Nov 2020 09:37:10
Stop Month and Year (derived)

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 18:51:06

FDA-CBER-2022-1614-6050895

US3542168
Folder: Screening
Form: Medical History (3)
Generated On: 26 Nov 2020 09:37:10
Stop Year (derived)

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 18:51:06

FDA-CBER-2022-1614-6050896

US3542168
Folder: Screening
Form: Medical History (4)
Generated On: 26 Nov 2020 09:37:10
Condition

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Sep 2020 18:52:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Sep 2020 18:52:54
Data point term sent to Coder	System	21 Sep 2020 18:51:41
User entered 'depression'	Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:51:14

FDA-CBER-2022-1614-6050897

US3542168
Folder: Screening
Form: Medical History (4)
Generated On: 26 Nov 2020 09:37:10
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered 'un UNK 2000'	Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:51:14

FDA-CBER-2022-1614-6050898

US3542168
Folder: Screening
Form: Medical History (4)
Generated On: 26 Nov 2020 09:37:10
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered '0'	Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:51:14

FDA-CBER-2022-1614-6050899

US3542168
Folder: Screening
Form: Medical History (4)
Generated On: 26 Nov 2020 09:37:10
Condition ongoing at study entry

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered 'Yes (Y)'	Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:51:14

FDA-CBER-2022-1614-6050900

US3542168
Folder: Screening
Form: Medical History (4)
Generated On: 26 Nov 2020 09:37:10
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered empty.	Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:51:14

FDA-CBER-2022-1614-6050901

US3542168
Folder: Screening
Form: Medical History (4)
Generated On: 26 Nov 2020 09:37:10
Stop date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered '0'	Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:51:14

FDA-CBER-2022-1614-6050902

US3542168
Folder: Screening
Form: Medical History (4)
Generated On: 26 Nov 2020 09:37:10
Start Month and Year (derived)

Audit	User	Time (GMT)
User entered 'Jan 2000'	System	21 Sep 2020 18:51:14

FDA-CBER-2022-1614-6050903

US3542168
Folder: Screening
Form: Medical History (4)
Generated On: 26 Nov 2020 09:37:10
Start Year (derived)

Audit	User	Time (GMT)
User entered '2000'	System	21 Sep 2020 18:51:14

FDA-CBER-2022-1614-6050904

US3542168
Folder: Screening
Form: Medical History (4)
Generated On: 26 Nov 2020 09:37:10
Stop Month and Year (derived)

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 18:51:14

FDA-CBER-2022-1614-6050905

US3542168
Folder: Screening
Form: Medical History (4)
Generated On: 26 Nov 2020 09:37:10
Stop Year (derived)

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 18:51:14

FDA-CBER-2022-1614-6050906

US3542168
Folder: Screening
Form: Medical History (5)
Generated On: 26 Nov 2020 09:37:10
Condition

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Stress disorders, PT: Post-traumatic stress disorder, LLT: Post-traumatic stress disorder - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Sep 2020 14:44:50
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 14:44:50
Data point term sent to Coder	System	30 Sep 2020 14:43:35
User entered 'PTSD'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:42:49

US3542168
Folder: Screening
Form: Medical History (5)
Generated On: 26 Nov 2020 09:37:10
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered 'UN UNK 2000'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:42:49

FDA-CBER-2022-1614-6050908

US3542168
Folder: Screening
Form: Medical History (5)
Generated On: 26 Nov 2020 09:37:10
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered '0'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:42:49

FDA-CBER-2022-1614-6050909

US3542168
Folder: Screening
Form: Medical History (5)
Generated On: 26 Nov 2020 09:37:10
Condition ongoing at study entry

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered 'Yes (Y)'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:42:49

FDA-CBER-2022-1614-6050910

US3542168
Folder: Screening
Form: Medical History (5)
Generated On: 26 Nov 2020 09:37:10
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered empty.	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:42:49

FDA-CBER-2022-1614-6050911

US3542168
Folder: Screening
Form: Medical History (5)
Generated On: 26 Nov 2020 09:37:10
Stop date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered '0'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:42:49

FDA-CBER-2022-1614-6050912

US3542168
Folder: Screening
Form: Medical History (5)
Generated On: 26 Nov 2020 09:37:10
Start Month and Year (derived)

Audit	User	Time (GMT)
User entered 'Jan 2000'	System	30 Sep 2020 14:42:49

FDA-CBER-2022-1614-6050913

US3542168
Folder: Screening
Form: Medical History (5)
Generated On: 26 Nov 2020 09:37:10
Start Year (derived)

Audit	User	Time (GMT)
User entered '2000'	System	30 Sep 2020 14:42:49

FDA-CBER-2022-1614-6050914

US3542168
Folder: Screening
Form: Medical History (5)
Generated On: 26 Nov 2020 09:37:10
Stop Month and Year (derived)

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 14:42:49

FDA-CBER-2022-1614-6050915

US3542168
Folder: Screening
Form: Medical History (5)
Generated On: 26 Nov 2020 09:37:10
Stop Year (derived)

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 14:42:49

FDA-CBER-2022-1614-6050916

US3542168
Folder: Screening
Form: Medical History (6)
Generated On: 26 Nov 2020 09:37:10
Condition

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User coded data point as SOC: Psychiatric disorders, HLGT: Personality disorders and disturbances in behaviour, HLT: Personality disorders with dramatic behaviour (Cluster B), PT: Borderline personality disorder, LLT: Borderline personality disorder - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Sep 2020 14:44:50
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 14:44:50
Data point term sent to Coder	System	30 Sep 2020 14:43:37
User entered 'Borderline personality disorder'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:43:02

FDA-CBER-2022-1614-6050917

US3542168
Folder: Screening
Form: Medical History (6)
Generated On: 26 Nov 2020 09:37:10
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered 'un UNK 2000'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:43:02

FDA-CBER-2022-1614-6050918

US3542168
Folder: Screening
Form: Medical History (6)
Generated On: 26 Nov 2020 09:37:10
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered '0'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:43:02

FDA-CBER-2022-1614-6050919

US3542168
Folder: Screening
Form: Medical History (6)
Generated On: 26 Nov 2020 09:37:10
Condition ongoing at study entry

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered 'Yes (Y)'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:43:02

FDA-CBER-2022-1614-6050920

US3542168
Folder: Screening
Form: Medical History (6)
Generated On: 26 Nov 2020 09:37:10
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered empty.	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:43:02

FDA-CBER-2022-1614-6050921

US3542168
Folder: Screening
Form: Medical History (6)
Generated On: 26 Nov 2020 09:37:10
Stop date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered '0'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:43:02

FDA-CBER-2022-1614-6050922

US3542168
Folder: Screening
Form: Medical History (6)
Generated On: 26 Nov 2020 09:37:10
Start Month and Year (derived)

Audit	User	Time (GMT)
User entered 'Jan 2000'	System	30 Sep 2020 14:43:02

FDA-CBER-2022-1614-6050923

US3542168
Folder: Screening
Form: Medical History (6)
Generated On: 26 Nov 2020 09:37:10
Start Year (derived)

Audit	User	Time (GMT)
User entered '2000'	System	30 Sep 2020 14:43:02

FDA-CBER-2022-1614-6050924

US3542168
Folder: Screening
Form: Medical History (6)
Generated On: 26 Nov 2020 09:37:10
Stop Month and Year (derived)

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 14:43:02

FDA-CBER-2022-1614-6050925

US3542168
Folder: Screening
Form: Medical History (6)
Generated On: 26 Nov 2020 09:37:10
Stop Year (derived)

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 14:43:02

FDA-CBER-2022-1614-6050926

US3542168
Folder: Screening
Form: Medical History (7)
Generated On: 26 Nov 2020 09:37:10
Condition

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User coded data point as SOC: Congenital, familial and genetic disorders, HLGT: Blood and lymphatic system disorders congenital, HLT: Haemoglobinopathies congenital, PT: Sickle cell disease, LLT: Sickle cell disease - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Sep 2020 14:44:50
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 14:44:50
Data point term sent to Coder	System	30 Sep 2020 14:43:38
User entered 'sickle cell disease'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:43:13

US3542168
Folder: Screening
Form: Medical History (7)
Generated On: 26 Nov 2020 09:37:10
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User closed query 'Start date is prior to Date of Birth. Please correct.' (Site from System).	System	30 Sep 2020 14:44:14
User entered 'UN (b) (6) 1966' reason for change: Data Entry Error	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:44:14
User opened query 'Start date is prior to Date of Birth. Please correct.' (Site from System).	System	30 Sep 2020 14:43:13
User entered 'un UNK 1966'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:43:13

US3542168
Folder: Screening
Form: Medical History (7)
Generated On: 26 Nov 2020 09:37:10
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered '0'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:43:13

FDA-CBER-2022-1614-6050929

US3542168
Folder: Screening
Form: Medical History (7)
Generated On: 26 Nov 2020 09:37:10
Condition ongoing at study entry

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered 'Yes (Y)'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:43:13

FDA-CBER-2022-1614-6050930

US3542168
Folder: Screening
Form: Medical History (7)
Generated On: 26 Nov 2020 09:37:10
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered empty.	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:43:13

FDA-CBER-2022-1614-6050931

US3542168
Folder: Screening
Form: Medical History (7)
Generated On: 26 Nov 2020 09:37:10
Stop date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered '0'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:43:13

FDA-CBER-2022-1614-6050932

US3542168
Folder: Screening
Form: Medical History (7)
Generated On: 26 Nov 2020 09:37:10
Start Month and Year (derived)

Audit	User	Time (GMT)
User entered (b) (6) 1966'	System	30 Sep 2020 14:44:14
User entered (b) (6) 1966'	System	30 Sep 2020 14:43:13

FDA-CBER-2022-1614-6050933

US3542168
Folder: Screening
Form: Medical History (7)
Generated On: 26 Nov 2020 09:37:10
Start Year (derived)

Audit	User	Time (GMT)
User entered '1966'	System	30 Sep 2020 14:43:13

FDA-CBER-2022-1614-6050934

US3542168
Folder: Screening
Form: Medical History (7)
Generated On: 26 Nov 2020 09:37:10
Stop Month and Year (derived)

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 14:43:13

FDA-CBER-2022-1614-6050935

US3542168
Folder: Screening
Form: Medical History (7)
Generated On: 26 Nov 2020 09:37:10
Stop Year (derived)

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 14:43:13

FDA-CBER-2022-1614-6050936

US3542168
Folder: Screening
Form: Medical History (8)
Generated On: 26 Nov 2020 09:37:10
Condition

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety disorders NEC, PT: Anxiety disorder, LLT: Anxiety disorder - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Sep 2020 14:44:50
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 14:44:50
Data point term sent to Coder	System	30 Sep 2020 14:43:38
User entered 'anxiety disorder'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:43:26

FDA-CBER-2022-1614-6050937

US3542168
Folder: Screening
Form: Medical History (8)
Generated On: 26 Nov 2020 09:37:10
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered 'un UNK 2000'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:43:26

FDA-CBER-2022-1614-6050938

US3542168
Folder: Screening
Form: Medical History (8)
Generated On: 26 Nov 2020 09:37:10
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered '0'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:43:26

FDA-CBER-2022-1614-6050939

US3542168
Folder: Screening
Form: Medical History (8)
Generated On: 26 Nov 2020 09:37:10
Condition ongoing at study entry

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered 'Yes (Y)'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:43:26

FDA-CBER-2022-1614-6050940

US3542168
Folder: Screening
Form: Medical History (8)
Generated On: 26 Nov 2020 09:37:10
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered empty.	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:43:26

FDA-CBER-2022-1614-6050941

US3542168
Folder: Screening
Form: Medical History (8)
Generated On: 26 Nov 2020 09:37:10
Stop date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered '0'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:43:26

FDA-CBER-2022-1614-6050942

US3542168
Folder: Screening
Form: Medical History (8)
Generated On: 26 Nov 2020 09:37:10
Start Month and Year (derived)

Audit	User	Time (GMT)
User entered 'Jan 2000'	System	30 Sep 2020 14:43:26

FDA-CBER-2022-1614-6050943

US3542168
Folder: Screening
Form: Medical History (8)
Generated On: 26 Nov 2020 09:37:10
Start Year (derived)

Audit	User	Time (GMT)
User entered '2000'	System	30 Sep 2020 14:43:26

FDA-CBER-2022-1614-6050944

US3542168
Folder: Screening
Form: Medical History (8)
Generated On: 26 Nov 2020 09:37:10
Stop Month and Year (derived)

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 14:43:26

FDA-CBER-2022-1614-6050945

US3542168
Folder: Screening
Form: Medical History (8)
Generated On: 26 Nov 2020 09:37:10
Stop Year (derived)

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 14:43:26

FDA-CBER-2022-1614-6050946

US3542168
Folder: Screening
Form: Vital Signs
Generated On: 26 Nov 2020 09:37:10
Were vital signs assessed?

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered 'Yes (Y)'	Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:20:42

FDA-CBER-2022-1614-6050947

US3542168
Folder: Screening
Form: Vital Signs
Generated On: 26 Nov 2020 09:37:10
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered '04 Sep 2020'	Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:20:42

FDA-CBER-2022-1614-6050948

US3542168
Folder: Screening
Form: Vital Signs
Generated On: 26 Nov 2020 09:37:10
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered '15:38'	Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:20:42

FDA-CBER-2022-1614-6050949

US3542168
Folder: Screening
Form: Vital Signs
Generated On: 26 Nov 2020 09:37:10
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
User entered '04 Sep 2020 15:38'	System	22 Sep 2020 15:20:42

FDA-CBER-2022-1614-6050950

US3542168
Folder: Screening
Form: Vital Signs
Generated On: 26 Nov 2020 09:37:10
Height *(xxx.x)*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered '68' in	Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:20:42
DataPoint set to visible.	System	04 Sep 2020 19:49:54

FDA-CBER-2022-1614-6050951

US3542168
Folder: Screening
Form: Vital Signs
Generated On: 26 Nov 2020 09:37:10
Weight *(xxx.x)*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered '145' lb	Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:20:42
DataPoint set to visible.	System	04 Sep 2020 19:49:54

FDA-CBER-2022-1614-6050952

US3542168
Folder: Screening
Form: Vital Signs
Generated On: 26 Nov 2020 09:37:10
BMI *(xxx.x)*

Audit	User	Time (GMT)
User entered '22.09327'	System	22 Sep 2020 15:20:42
DataPoint set to visible.	System	04 Sep 2020 19:49:54

FDA-CBER-2022-1614-6050953

US3542168
Folder: Screening
Form: Vital Signs
Generated On: 26 Nov 2020 09:37:10
BMI units

Audit	User	Time (GMT)
User entered 'kg/m2'	System	22 Sep 2020 15:20:42
DataPoint set to visible.	System	04 Sep 2020 19:49:54

FDA-CBER-2022-1614-6050954

US3542168
Folder: Screening
Form: Vital Signs
Generated On: 26 Nov 2020 09:37:10
Temperature *(xxx.x)*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered missing code ND - Not Done.	Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:20:42

FDA-CBER-2022-1614-6050955

US3542168
Folder: Screening
Form: Vital Signs
Generated On: 26 Nov 2020 09:37:10
Route of measurement

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered empty.	Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:20:42

FDA-CBER-2022-1614-6050956

US3542168
Folder: Screening
Form: Vital Signs
Generated On: 26 Nov 2020 09:37:10
If Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered empty.	Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:20:42

FDA-CBER-2022-1614-6050957

US3542168
Folder: Screening
Form: Vital Signs
Generated On: 26 Nov 2020 09:37:10
Pulse *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered missing code ND - Not Done.	Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:20:42

FDA-CBER-2022-1614-6050958

US3542168
Folder: Screening
Form: Vital Signs
Generated On: 26 Nov 2020 09:37:10
Pulse units

Audit	User	Time (GMT)
User entered 'bpm'	System	22 Sep 2020 15:20:42

FDA-CBER-2022-1614-6050959

US3542168
Folder: Screening
Form: Vital Signs
Generated On: 26 Nov 2020 09:37:10
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered missing code ND - Not Done.	Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:20:42

FDA-CBER-2022-1614-6050960

US3542168
Folder: Screening
Form: Vital Signs
Generated On: 26 Nov 2020 09:37:10
Respiratory Rate units

Audit	User	Time (GMT)
User entered 'breaths/min'	System	22 Sep 2020 15:20:42

FDA-CBER-2022-1614-6050961

US3542168
Folder: Screening
Form: Vital Signs
Generated On: 26 Nov 2020 09:37:10
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered missing code ND - Not Done.	Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:20:42

FDA-CBER-2022-1614-6050962

US3542168
Folder: Screening
Form: Vital Signs
Generated On: 26 Nov 2020 09:37:10
Systolic Blood Pressure units

Audit	User	Time (GMT)
User entered 'mmHg'	System	22 Sep 2020 15:20:42

FDA-CBER-2022-1614-6050963

US3542168
Folder: Screening
Form: Vital Signs
Generated On: 26 Nov 2020 09:37:10
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered missing code ND - Not Done.	Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:20:42

FDA-CBER-2022-1614-6050964

US3542168
Folder: Screening
Form: Vital Signs
Generated On: 26 Nov 2020 09:37:10
Diastolic Blood Pressure units

Audit	User	Time (GMT)
User entered 'mmHg'	System	22 Sep 2020 15:20:42

FDA-CBER-2022-1614-6050965

US3542168
Folder: Screening
Form: Physical Examination
Generated On: 26 Nov 2020 09:37:10
Was the physical examination performed?

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered 'No (N)'	Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:20:21

FDA-CBER-2022-1614-6050966

US3542168
Folder: Screening
Form: Physical Examination
Generated On: 26 Nov 2020 09:37:10
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered empty.	Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:20:21

FDA-CBER-2022-1614-6050967

US3542168
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 09:37:10
Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered 'No (N)'	Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:23:04

FDA-CBER-2022-1614-6050968

US3542168
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 09:37:10
Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered 'No (N)'	Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:23:04

FDA-CBER-2022-1614-6050969

US3542168
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 09:37:10
Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered 'No (N)'	Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:23:04

FDA-CBER-2022-1614-6050970

US3542168
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 09:37:10
Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered 'Yes (Y)'	Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:23:04

FDA-CBER-2022-1614-6050971

US3542168
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 09:37:10
Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered 'No (N)'	Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:23:04

FDA-CBER-2022-1614-6050972

US3542168
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 09:37:10
Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered 'No (N)'	Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:23:04

FDA-CBER-2022-1614-6050973

US3542168
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 09:37:10
Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered 'No (N)'	Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:23:04

FDA-CBER-2022-1614-6050974

US3542168
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 09:37:10
Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered 'No (N)'	Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:23:04

FDA-CBER-2022-1614-6050975

US3542168
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 09:37:10
Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered 'No (N)'	Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:23:04

FDA-CBER-2022-1614-6050976

US3542168
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 09:37:10
Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered 'No (N)'	Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:23:04

FDA-CBER-2022-1614-6050977

US3542168
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 09:37:10
Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered 'No (N)'	Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:23:04

FDA-CBER-2022-1614-6050978

US3542168
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 09:37:10
Other

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered 'No (N)'	Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:23:04

FDA-CBER-2022-1614-6050979

US3542168
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 09:37:10
Specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered empty.	Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:23:04

FDA-CBER-2022-1614-6050980

US3542168
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 09:37:10
No Risk Identified

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered '0'	Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:23:04

FDA-CBER-2022-1614-6050981

US3542168
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 09:37:10
Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered '0'	Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:23:04

FDA-CBER-2022-1614-6050982

US3542168
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 09:37:10
Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered '0'	Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:23:04

US3542168
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 09:37:10
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered '0'	Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:23:04

FDA-CBER-2022-1614-6050984

US3542168
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 09:37:10
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered '0'	Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:23:04

FDA-CBER-2022-1614-6050985

US3542168
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 09:37:10
Resides in a single family home (i.e., detached housing)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered '1'	Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:23:04

FDA-CBER-2022-1614-6050986

US3542168
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 09:37:10
Other

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered '0'	Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:23:04

FDA-CBER-2022-1614-6050987

US3542168
Folder: Screening
Form: Risk of Exposure
Generated On: 26 Nov 2020 09:37:10
Specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered empty.	Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:23:04

FDA-CBER-2022-1614-6050988

US3542168
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 26 Nov 2020 09:37:10
Was this visit performed?

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:50:51
User entered 'Yes (Y)'	Elissa Malkin (b) (4) (b) (4)	04 Sep 2020 20:20:10

FDA-CBER-2022-1614-6050989

US3542168
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 26 Nov 2020 09:37:10
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:50:51
User entered '4 Sep 2020'	Elissa Malkin (b) (4) (b) (4)	04 Sep 2020 20:20:10

FDA-CBER-2022-1614-6050990

US3542168
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 26 Nov 2020 09:37:10
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:50:51
User entered 'Clinic (Clinic)'	Elissa Malkin (b) (4) (b) (4)	04 Sep 2020 20:20:10

FDA-CBER-2022-1614-6050991

US3542168
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 26 Nov 2020 09:37:10
Folder OID

Audit	User	Time (GMT)
User entered 'VISIT1'	System	04 Sep 2020 20:20:10

FDA-CBER-2022-1614-6050992

US3542168
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 26 Nov 2020 09:37:10
What was the date of randomization? *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:50:51
User entered '04 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 19:49:35

FDA-CBER-2022-1614-6050993

US3542168
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 26 Nov 2020 09:37:10
What was the participant's randomization number?

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:50:51
User entered '111966'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 19:49:35

FDA-CBER-2022-1614-6050994

US3542168
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 26 Nov 2020 09:37:10
In what Cohort was the participant enrolled?

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:50:51
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 19:49:35

FDA-CBER-2022-1614-6050995

US3542168
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 26 Nov 2020 09:37:10
Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered 'No (N)'	Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:19:58

FDA-CBER-2022-1614-6050996

US3542168
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 26 Nov 2020 09:37:10
Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered 'No (N)'	Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:19:58

FDA-CBER-2022-1614-6050997

US3542168
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 26 Nov 2020 09:37:10
Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered 'No (N)'	Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:19:58

FDA-CBER-2022-1614-6050998

US3542168
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 26 Nov 2020 09:37:10
Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered 'No (N)'	Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:19:58

FDA-CBER-2022-1614-6050999

US3542168
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 26 Nov 2020 09:37:10
Liver Disease

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered 'No (N)'	Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:19:58

FDA-CBER-2022-1614-6051000

US3542168
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 26 Nov 2020 09:37:10
Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered 'No (N)'	Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:19:58
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 05:29:34
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 05:29:32

FDA-CBER-2022-1614-6051001

US3542168
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 26 Nov 2020 09:37:10
Height

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered missing code ND - Not Done.	Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:21:21

FDA-CBER-2022-1614-6051002

US3542168
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 26 Nov 2020 09:37:10
Weight

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered missing code ND - Not Done.	Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:21:21

FDA-CBER-2022-1614-6051003

US3542168
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 26 Nov 2020 09:37:10
Height

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered missing code ND - Not Done.	Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:21:21

FDA-CBER-2022-1614-6051004

US3542168
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 26 Nov 2020 09:37:10
Weight

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered missing code ND - Not Done.	Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:21:21

FDA-CBER-2022-1614-6051005

US3542168
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 09:37:10
Timepoint

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:21:21

FDA-CBER-2022-1614-6051006

US3542168
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 09:37:10
Were vital signs assessed?

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered 'Yes (Y)'	Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:21:21

FDA-CBER-2022-1614-6051007

US3542168
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 09:37:10
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered '04 Sep 2020'	Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:21:21

FDA-CBER-2022-1614-6051008

US3542168
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 09:37:10
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered '15:38'	Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:21:21

FDA-CBER-2022-1614-6051009

US3542168
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 09:37:10
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
User entered '04 Sep 2020 15:38'	System	22 Sep 2020 15:21:21

FDA-CBER-2022-1614-6051010

US3542168
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 09:37:10
Temperature *(xxx.x)*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered '98.8' F	Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:21:21

FDA-CBER-2022-1614-6051011

US3542168
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 09:37:10
Route of measurement

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered 'Oral (Oral)'	Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:21:21

FDA-CBER-2022-1614-6051012

US3542168
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 09:37:10
If Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered empty.	Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:21:21

FDA-CBER-2022-1614-6051013

US3542168
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 09:37:10
Pulse *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered '56'	Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:21:21

FDA-CBER-2022-1614-6051014

US3542168
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 09:37:10
Pulse units

Audit	User	Time (GMT)
User entered 'bpm'	System	22 Sep 2020 15:21:21

FDA-CBER-2022-1614-6051015

US3542168
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 09:37:10
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered '16'	Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:21:21

FDA-CBER-2022-1614-6051016

US3542168
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 09:37:10
Respiratory Rate units

Audit	User	Time (GMT)
User entered 'breaths/min'	System	22 Sep 2020 15:21:21

FDA-CBER-2022-1614-6051017

US3542168
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 09:37:10
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered '154'	Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:21:21

FDA-CBER-2022-1614-6051018

US3542168
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 09:37:10
Systolic Blood Pressure units

Audit	User	Time (GMT)
User entered 'mmHg'	System	22 Sep 2020 15:21:21

FDA-CBER-2022-1614-6051019

US3542168
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 09:37:10
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered '92'	Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:21:21

FDA-CBER-2022-1614-6051020

US3542168
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 09:37:10
Diastolic Blood Pressure units

Audit	User	Time (GMT)
User entered 'mmHg'	System	22 Sep 2020 15:21:21

FDA-CBER-2022-1614-6051021

US3542168
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 26 Nov 2020 09:37:10
Height

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered missing code ND - Not Done.	Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:21:21

FDA-CBER-2022-1614-6051022

US3542168
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 26 Nov 2020 09:37:10
Weight

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered missing code ND - Not Done.	Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:21:21

FDA-CBER-2022-1614-6051023

US3542168
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 09:37:10
Timepoint

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:23:58

FDA-CBER-2022-1614-6051024

US3542168
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 09:37:10
Were vital signs assessed?

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered 'Yes (Y)'	Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:23:58

FDA-CBER-2022-1614-6051025

US3542168
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 09:37:10
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered '04 Sep 2020'	Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:23:58

FDA-CBER-2022-1614-6051026

US3542168
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 09:37:10
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered '16:48'	Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:23:58

FDA-CBER-2022-1614-6051027

US3542168
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 09:37:10
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
User entered '04 Sep 2020 16:48'	System	22 Sep 2020 15:23:58

FDA-CBER-2022-1614-6051028

US3542168
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 09:37:10
Temperature *(xxx.x)*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered '98.8' F	Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:23:58

FDA-CBER-2022-1614-6051029

US3542168
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 09:37:10
Route of measurement

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered 'Oral (Oral)'	Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:23:58

FDA-CBER-2022-1614-6051030

US3542168
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 09:37:10
If Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered empty.	Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:23:58

FDA-CBER-2022-1614-6051031

US3542168
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 09:37:10
Pulse *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered '60'	Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:23:58

FDA-CBER-2022-1614-6051032

US3542168
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 09:37:10
Pulse units

Audit	User	Time (GMT)
User entered 'bpm'	System	22 Sep 2020 15:23:58

FDA-CBER-2022-1614-6051033

US3542168
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 09:37:10
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered '16'	Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:23:58

FDA-CBER-2022-1614-6051034

US3542168
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 09:37:10
Respiratory Rate units

Audit	User	Time (GMT)
User entered 'breaths/min'	System	22 Sep 2020 15:23:58

FDA-CBER-2022-1614-6051035

US3542168
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 09:37:10
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered '144'	Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:23:58

FDA-CBER-2022-1614-6051036

US3542168
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 09:37:10
Systolic Blood Pressure units

Audit	User	Time (GMT)
User entered 'mmHg'	System	22 Sep 2020 15:23:58

FDA-CBER-2022-1614-6051037

US3542168
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 09:37:10
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered '94'	Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:23:58

FDA-CBER-2022-1614-6051038

US3542168
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 09:37:10
Diastolic Blood Pressure units

Audit	User	Time (GMT)
User entered 'mmHg'	System	22 Sep 2020 15:23:58

FDA-CBER-2022-1614-6051039

US3542168
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 26 Nov 2020 09:37:10
Was the physical examination performed?

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered 'Yes (Y)'	Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:20:15

FDA-CBER-2022-1614-6051040

US3542168
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 26 Nov 2020 09:37:10
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered '04 Sep 2020'	Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:20:15

FDA-CBER-2022-1614-6051041

US3542168
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 26 Nov 2020 09:37:10
Was study treatment given?

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:50:51
User entered 'Yes (Y)'	Elissa Malkin (b) (4) (b) (4)	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051042

US3542168
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 26 Nov 2020 09:37:10
If No, reason not given

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:50:51
User entered empty.	Elissa Malkin (b) (4) (b) (4)	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051043

US3542168
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 26 Nov 2020 09:37:10
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:50:51
User entered empty.	Elissa Malkin (b) (4) (b) (4)	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051044

US3542168
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 26 Nov 2020 09:37:10
What was the study treatment?

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051045

US3542168
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 26 Nov 2020 09:37:10
What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:50:51
User entered '4 Sep 2020'	Elissa Malkin (b) (4) (b) (4)	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051046

US3542168
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 26 Nov 2020 09:37:10
What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:50:51
User entered '16:18'	Elissa Malkin (b) (4) (b) (4)	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051047

US3542168
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 26 Nov 2020 09:37:10
Treatment Date and Time (derived)

Audit	User	Time (GMT)
User entered '4 Sep 2020 16:18'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051048

US3542168
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 26 Nov 2020 09:37:10
Which arm was used to give treatment?

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	05 Sep 2020 21:50:51
User entered 'Left Arm (LEFT ARM)'	Elissa Malkin (b) (4) (b) (4)	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051049

US3542168
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 26 Nov 2020 09:37:10
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
User entered 'ONCE'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051050

US3542168
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 26 Nov 2020 09:37:10
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051051

US3542168
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 26 Nov 2020 09:37:10
Was the sample collected?

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered 'Yes (Y)'	Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:23:22

FDA-CBER-2022-1614-6051052

US3542168
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 26 Nov 2020 09:37:10
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered '04 Sep 2020'	Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:23:22

FDA-CBER-2022-1614-6051053

US3542168
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 26 Nov 2020 09:37:10
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered '15:56'	Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:23:22

FDA-CBER-2022-1614-6051054

US3542168
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 26 Nov 2020 09:37:10
Collection date and time (derived)

Audit	User	Time (GMT)
User entered '04 Sep 2020 15:56'	System	22 Sep 2020 15:23:22

FDA-CBER-2022-1614-6051055

US3542168
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab
Generated On: 26 Nov 2020 09:37:10
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered '04 Sep 2020'	Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:23:33

FDA-CBER-2022-1614-6051056

US3542168
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 26 Nov 2020 09:37:10
Lab Test

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:23:33

FDA-CBER-2022-1614-6051057

US3542168
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 26 Nov 2020 09:37:10
Was the sample collected?

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered 'Yes (Y)'	Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:23:33

FDA-CBER-2022-1614-6051058

US3542168
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 26 Nov 2020 09:37:10
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered '15:58'	Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:23:33

FDA-CBER-2022-1614-6051059

US3542168
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 26 Nov 2020 09:37:10
Collection date and time (derived)

Audit	User	Time (GMT)
User entered '04 Sep 2020 15:58'	System	22 Sep 2020 15:23:33

FDA-CBER-2022-1614-6051060

US3542168
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 26 Nov 2020 09:37:10
Lab Test

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:23:33

FDA-CBER-2022-1614-6051061

US3542168
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 26 Nov 2020 09:37:10
Was the sample collected?

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered 'No (N)'	Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:23:33

FDA-CBER-2022-1614-6051062

US3542168
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 26 Nov 2020 09:37:10
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered empty.	Taylor Ladson (b) (4) (b) (4)	22 Sep 2020 15:23:33

FDA-CBER-2022-1614-6051063

US3542168
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 26 Nov 2020 09:37:10
Collection date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 15:23:33

FDA-CBER-2022-1614-6051064

US3542168
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 26 Nov 2020 09:37:10
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	17 Sep 2020 04:28:58
User entered 'Yes (Y)'	Madhu Balachandran (b) (4)	16 Sep 2020 18:41:38

FDA-CBER-2022-1614-6051065

US3542168
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 26 Nov 2020 09:37:10
Continuing Flag

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 18:41:38

FDA-CBER-2022-1614-6051066

US3542168
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 26 Nov 2020 09:37:10
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051067

US3542168
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 26 Nov 2020 09:37:10
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-04T16:52:01', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '9b59e169-ca1d-493c-935e-d14a027d5f70'	System	04 Sep 2020 20:52:33
User entered 'Yes (Y)'	System	04 Sep 2020 20:52:33

FDA-CBER-2022-1614-6051068

US3542168
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 26 Nov 2020 09:37:10
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-04T16:52:12', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '9b59e169-ca1d-493c-935e-d14a027d5f70'	System	04 Sep 2020 20:52:33
User entered '98.8'	System	04 Sep 2020 20:52:33

FDA-CBER-2022-1614-6051069

US3542168
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 26 Nov 2020 09:37:10
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-04T16:52:20', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '9b59e169-ca1d-493c-935e-d14a027d5f70'	System	04 Sep 2020 20:52:33
User entered 'No (N)'	System	04 Sep 2020 20:52:33

US3542168
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 26 Nov 2020 09:37:10
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-04T16:52:29', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '9b59e169-ca1d-493c-935e-d14a027d5f70'	System	04 Sep 2020 20:52:33
User entered '04 Sep 2020 16:52'	System	04 Sep 2020 20:52:33

FDA-CBER-2022-1614-6051071

US3542168
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 26 Nov 2020 09:37:10
PC Open Date & Time

Audit	User	Time (GMT)
User entered '04 Sep 2020 16:38'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051072

US3542168
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 26 Nov 2020 09:37:10
PC Close Date & Time

Audit	User	Time (GMT)
User entered '04 Sep 2020 19:08'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051073

US3542168
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 26 Nov 2020 09:37:10
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051074

US3542168
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 26 Nov 2020 09:37:10
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-04T20:12:14', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '4e571d18-005a-4f9d-8ee4-43d816fcb424'	System	05 Sep 2020 00:12:35
User entered 'Yes (Y)'	System	05 Sep 2020 00:12:35

FDA-CBER-2022-1614-6051075

US3542168
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 26 Nov 2020 09:37:10
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-04T20:12:21', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '4e571d18-005a-4f9d-8ee4-43d816fcb424'	System	05 Sep 2020 00:12:35
User entered '98.3'	System	05 Sep 2020 00:12:35

US3542168
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 26 Nov 2020 09:37:10
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-04T20:12:25', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '4e571d18-005a-4f9d-8ee4-43d816fcb424'	System	05 Sep 2020 00:12:35
User entered 'No (N)'	System	05 Sep 2020 00:12:35

US3542168
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 26 Nov 2020 09:37:10
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-04T20:12:32', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '4e571d18-005a-4f9d-8ee4-43d816fcb424'	System	05 Sep 2020 00:12:35
User entered '04 Sep 2020 20:12'	System	05 Sep 2020 00:12:35

US3542168
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 26 Nov 2020 09:37:10
PC Open Date & Time

Audit	User	Time (GMT)
User entered '04 Sep 2020 20:03'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051079

US3542168
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 26 Nov 2020 09:37:10
PC Close Date & Time

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051080

US3542168
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 26 Nov 2020 09:37:10
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 2'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051081

US3542168
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 26 Nov 2020 09:37:10
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-05T13:02:49', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '78427212-8449-4879-906d-f8070abc8f03'	System	05 Sep 2020 17:03:15
User entered 'Yes (Y)'	System	05 Sep 2020 17:03:15

FDA-CBER-2022-1614-6051082

US3542168
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 26 Nov 2020 09:37:10
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-05T13:03:02', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '78427212-8449-4879-906d-f8070abc8f03'	System	05 Sep 2020 17:03:15
User entered '98.3'	System	05 Sep 2020 17:03:15

FDA-CBER-2022-1614-6051083

US3542168
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 26 Nov 2020 09:37:10
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-05T13:03:06', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '78427212-8449-4879-906d-f8070abc8f03'	System	05 Sep 2020 17:03:15
User entered 'No (N)'	System	05 Sep 2020 17:03:15

US3542168
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 26 Nov 2020 09:37:10
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-05T13:03:12', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '78427212-8449-4879-906d-f8070abc8f03'	System	05 Sep 2020 17:03:15
User entered '05 Sep 2020 13:03'	System	05 Sep 2020 17:03:15

FDA-CBER-2022-1614-6051085

US3542168
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 26 Nov 2020 09:37:10
PC Open Date & Time

Audit	User	Time (GMT)
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051086

US3542168
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 26 Nov 2020 09:37:10
PC Close Date & Time

Audit	User	Time (GMT)
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051087

US3542168
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 26 Nov 2020 09:37:10
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 3'	System	04 Sep 2020 20:20:50

US3542168
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 26 Nov 2020 09:37:10
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-06T17:00:32', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'eb6740ff-0af2-490e-b82c-0fffb47a0d5b'	System	06 Sep 2020 21:01:04
User entered 'Yes (Y)'	System	06 Sep 2020 21:01:04

US3542168
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 26 Nov 2020 09:37:10
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-06T17:00:43', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'eb6740ff-0af2-490e-b82c-0fffb47a0d5b'	System	06 Sep 2020 21:01:04
User entered '98.6'	System	06 Sep 2020 21:01:04

FDA-CBER-2022-1614-6051090

US3542168
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 26 Nov 2020 09:37:10
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-06T17:00:47', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'eb6740ff-0af2-490e-b82c-0fffb47a0d5b'	System	06 Sep 2020 21:01:04
User entered 'No (N)'	System	06 Sep 2020 21:01:04

US3542168
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 26 Nov 2020 09:37:10
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-06T17:00:59', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'eb6740ff-0af2-490e-b82c-0fffb47a0d5b'	System	06 Sep 2020 21:01:04
User entered '06 Sep 2020 17:00'	System	06 Sep 2020 21:01:04

FDA-CBER-2022-1614-6051092

US3542168
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 26 Nov 2020 09:37:10
PC Open Date & Time

Audit	User	Time (GMT)
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051093

US3542168
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 26 Nov 2020 09:37:10
PC Close Date & Time

Audit	User	Time (GMT)
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051094

US3542168
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 26 Nov 2020 09:37:10
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 4'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051095

US3542168
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 26 Nov 2020 09:37:10
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-07T13:20:41', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'c4806377-450a-4231-b4da-dd1e033de11e'	System	07 Sep 2020 17:21:14
User entered 'Yes (Y)'	System	07 Sep 2020 17:21:14

FDA-CBER-2022-1614-6051096

US3542168
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 26 Nov 2020 09:37:10
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-07T13:20:59', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'c4806377-450a-4231-b4da-dd1e033de11e'	System	07 Sep 2020 17:21:14
User entered '98.7'	System	07 Sep 2020 17:21:14

FDA-CBER-2022-1614-6051097

US3542168
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 26 Nov 2020 09:37:10
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-07T13:21:04', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'c4806377-450a-4231-b4da-dd1e033de11e'	System	07 Sep 2020 17:21:14
User entered 'No (N)'	System	07 Sep 2020 17:21:14

US3542168
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 26 Nov 2020 09:37:10
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-07T13:21:10', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'c4806377-450a-4231-b4da-dd1e033de11e'	System	07 Sep 2020 17:21:14
User entered '07 Sep 2020 13:21'	System	07 Sep 2020 17:21:14

FDA-CBER-2022-1614-6051099

US3542168
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 26 Nov 2020 09:37:10
PC Open Date & Time

Audit	User	Time (GMT)
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051100

US3542168
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 26 Nov 2020 09:37:10
PC Close Date & Time

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051101

US3542168
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 26 Nov 2020 09:37:10
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 5'	System	04 Sep 2020 20:20:50

US3542168
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 26 Nov 2020 09:37:10
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-08T13:25:32', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'c0855a52-701d-4819-aa3d-a2cf0dd1e8dc'	System	08 Sep 2020 17:25:53
User entered 'Yes (Y)'	System	08 Sep 2020 17:25:53

FDA-CBER-2022-1614-6051103

US3542168
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 26 Nov 2020 09:37:10
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-08T13:25:41', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'c0855a52-701d-4819-aa3d-a2cf0dd1e8dc'	System	08 Sep 2020 17:25:53
User entered '97.8'	System	08 Sep 2020 17:25:53

US3542168
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 26 Nov 2020 09:37:10
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-08T13:25:45', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'c0855a52-701d-4819-aa3d-a2cf0dd1e8dc'	System	08 Sep 2020 17:25:53
User entered 'No (N)'	System	08 Sep 2020 17:25:53

US3542168
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 26 Nov 2020 09:37:10
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-08T13:25:48', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'c0855a52-701d-4819-aa3d-a2cf0dd1e8dc'	System	08 Sep 2020 17:25:53
User entered '08 Sep 2020 13:25'	System	08 Sep 2020 17:25:53

US3542168
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 26 Nov 2020 09:37:10
PC Open Date & Time

Audit	User	Time (GMT)
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051107

US3542168
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 26 Nov 2020 09:37:10
PC Close Date & Time

Audit	User	Time (GMT)
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051108

US3542168
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 26 Nov 2020 09:37:10
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 6'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051109

US3542168
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 26 Nov 2020 09:37:10
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-09T12:07:48', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '2130783b-21c1-4d6e-b9b1-c5ab0d76e524'	System	09 Sep 2020 16:08:08
User entered 'Yes (Y)'	System	09 Sep 2020 16:08:08

FDA-CBER-2022-1614-6051110

US3542168
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 26 Nov 2020 09:37:10
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-09T12:07:55', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '2130783b-21c1-4d6e-b9b1-c5ab0d76e524'	System	09 Sep 2020 16:08:08
User entered '98.2'	System	09 Sep 2020 16:08:08

US3542168
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 26 Nov 2020 09:37:10
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-09T12:08:00', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '2130783b-21c1-4d6e-b9b1-c5ab0d76e524'	System	09 Sep 2020 16:08:08
User entered 'No (N)'	System	09 Sep 2020 16:08:08

FDA-CBER-2022-1614-6051112

US3542168
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 26 Nov 2020 09:37:10
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-09T12:08:03', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '2130783b-21c1-4d6e-b9b1-c5ab0d76e524'	System	09 Sep 2020 16:08:08
User entered '09 Sep 2020 12:08'	System	09 Sep 2020 16:08:08

US3542168
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 26 Nov 2020 09:37:10
PC Open Date & Time

Audit	User	Time (GMT)
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051114

US3542168
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 26 Nov 2020 09:37:10
PC Close Date & Time

Audit	User	Time (GMT)
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051115

US3542168
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 26 Nov 2020 09:37:10
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 7'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051116

US3542168
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 26 Nov 2020 09:37:10
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-10T20:30:23', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '86f77b5f-e594-48d4-8610-07893b7bd754'	System	11 Sep 2020 00:30:46
User entered 'Yes (Y)'	System	11 Sep 2020 00:30:46

FDA-CBER-2022-1614-6051117

US3542168
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 26 Nov 2020 09:37:10
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-10T20:30:30', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '86f77b5f-e594-48d4-8610-07893b7bd754'	System	11 Sep 2020 00:30:46
User entered '98.4'	System	11 Sep 2020 00:30:46

FDA-CBER-2022-1614-6051118

US3542168
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 26 Nov 2020 09:37:10
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-10T20:30:35', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '86f77b5f-e594-48d4-8610-07893b7bd754'	System	11 Sep 2020 00:30:46
User entered 'No (N)'	System	11 Sep 2020 00:30:46

FDA-CBER-2022-1614-6051119

US3542168
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 26 Nov 2020 09:37:10
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-10T20:30:40', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '86f77b5f-e594-48d4-8610-07893b7bd754'	System	11 Sep 2020 00:30:46
User entered '10 Sep 2020 20:30'	System	11 Sep 2020 00:30:46

US3542168
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 26 Nov 2020 09:37:10
PC Open Date & Time

Audit	User	Time (GMT)
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051121

US3542168
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 26 Nov 2020 09:37:10
PC Close Date & Time

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051122

US3542168
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 26 Nov 2020 09:37:10
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051123

US3542168
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 26 Nov 2020 09:37:10
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-04T16:52:48', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'f56cc5cc-1620-4450-9217-efceaa79aaf0'	System	04 Sep 2020 20:53:16
User entered 'Does not interfere with activity (2)'	System	04 Sep 2020 20:53:16

US3542168
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 26 Nov 2020 09:37:10
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-04T16:52:55', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'f56cc5cc-1620-4450-9217-efceaa79aaf0'	System	04 Sep 2020 20:53:16
User entered 'No (N)'	System	04 Sep 2020 20:53:16

US3542168
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 26 Nov 2020 09:37:10
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-04T16:53:00', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'f56cc5cc-1620-4450-9217-efceaa79aaf0'	System	04 Sep 2020 20:53:16
User entered 'No (N)'	System	04 Sep 2020 20:53:16

US3542168
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 26 Nov 2020 09:37:10
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-04T16:53:07', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'f56cc5cc-1620-4450-9217-efceaa79aaf0'	System	04 Sep 2020 20:53:16
User entered 'None (1)'	System	04 Sep 2020 20:53:16

US3542168
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 26 Nov 2020 09:37:10
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-04T16:53:12', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'f56cc5cc-1620-4450-9217-efceaa79aaf0'	System	04 Sep 2020 20:53:16
User entered '04 Sep 2020 16:53'	System	04 Sep 2020 20:53:16

US3542168
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 26 Nov 2020 09:37:10
PC Open Date & Time

Audit	User	Time (GMT)
User entered '04 Sep 2020 16:38'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051129

US3542168
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 26 Nov 2020 09:37:10
PC Close Date & Time

Audit	User	Time (GMT)
User entered '04 Sep 2020 19:08'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051130

US3542168
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 26 Nov 2020 09:37:10
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051131

US3542168
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 26 Nov 2020 09:37:10
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-04T20:12:40', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'b588eef7-ada2-46a8-bf66-cdad9932bdad'	System	05 Sep 2020 00:13:01
User entered 'None (1)'	System	05 Sep 2020 00:13:01

US3542168
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 26 Nov 2020 09:37:10
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-04T20:12:43', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'b588eef7-ada2-46a8-bf66-cdad9932bdad'	System	05 Sep 2020 00:13:01
User entered 'No (N)'	System	05 Sep 2020 00:13:01

US3542168
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 26 Nov 2020 09:37:10
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-04T20:12:47', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'b588eef7-ada2-46a8-bf66-cdad9932bdad'	System	05 Sep 2020 00:13:01
User entered 'No (N)'	System	05 Sep 2020 00:13:01

US3542168
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 26 Nov 2020 09:37:10
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-04T20:12:52', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'b588eef7-ada2-46a8-bf66-cdad9932bdad'	System	05 Sep 2020 00:13:01
User entered 'None (1)'	System	05 Sep 2020 00:13:01

FDA-CBER-2022-1614-6051135

US3542168
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 26 Nov 2020 09:37:10
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-04T20:12:59', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'b588eef7-ada2-46a8-bf66-cdad9932bdad'	System	05 Sep 2020 00:13:01
User entered '04 Sep 2020 20:12'	System	05 Sep 2020 00:13:01

US3542168
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 26 Nov 2020 09:37:10
PC Open Date & Time

Audit	User	Time (GMT)
User entered '04 Sep 2020 20:03'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051137

US3542168
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 26 Nov 2020 09:37:10
PC Close Date & Time

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051138

US3542168
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 26 Nov 2020 09:37:10
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 2'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051139

US3542168
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 26 Nov 2020 09:37:10
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-05T13:03:19', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '1630f32c-1ad1-441c-9871-61b77560b2e1'	System	05 Sep 2020 17:03:40
User entered 'None (1)'	System	05 Sep 2020 17:03:40

FDA-CBER-2022-1614-6051140

US3542168
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 26 Nov 2020 09:37:10
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-05T13:03:23', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '1630f32c-1ad1-441c-9871-61b77560b2e1'	System	05 Sep 2020 17:03:40
User entered 'No (N)'	System	05 Sep 2020 17:03:40

US3542168
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 26 Nov 2020 09:37:10
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-05T13:03:29', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '1630f32c-1ad1-441c-9871-61b77560b2e1'	System	05 Sep 2020 17:03:40
User entered 'No (N)'	System	05 Sep 2020 17:03:40

FDA-CBER-2022-1614-6051142

US3542168
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 26 Nov 2020 09:37:10
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-05T13:03:33', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '1630f32c-1ad1-441c-9871-61b77560b2e1'	System	05 Sep 2020 17:03:40
User entered 'None (1)'	System	05 Sep 2020 17:03:40

US3542168
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 26 Nov 2020 09:37:10
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-05T13:03:36', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '1630f32c-1ad1-441c-9871-61b77560b2e1'	System	05 Sep 2020 17:03:40
User entered '05 Sep 2020 13:03'	System	05 Sep 2020 17:03:40

FDA-CBER-2022-1614-6051144

US3542168
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 26 Nov 2020 09:37:10
PC Open Date & Time

Audit	User	Time (GMT)
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051145

US3542168
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 26 Nov 2020 09:37:10
PC Close Date & Time

Audit	User	Time (GMT)
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051146

US3542168
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 26 Nov 2020 09:37:10
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 3'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051147

US3542168
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 26 Nov 2020 09:37:10
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-06T17:01:11', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '21edc182-8f82-46d3-96f5-025d9c6ec6d4'	System	06 Sep 2020 21:01:39
User entered 'None (1)'	System	06 Sep 2020 21:01:39

FDA-CBER-2022-1614-6051148

US3542168
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 26 Nov 2020 09:37:10
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-06T17:01:20', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '21edc182-8f82-46d3-96f5-025d9c6ec6d4'	System	06 Sep 2020 21:01:39
User entered 'No (N)'	System	06 Sep 2020 21:01:39

US3542168
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 26 Nov 2020 09:37:10
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-06T17:01:25', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '21edc182-8f82-46d3-96f5-025d9c6ec6d4'	System	06 Sep 2020 21:01:39
User entered 'No (N)'	System	06 Sep 2020 21:01:39

US3542168
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 26 Nov 2020 09:37:10
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-06T17:01:30', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '21edc182-8f82-46d3-96f5-025d9c6ec6d4'	System	06 Sep 2020 21:01:39
User entered 'None (1)'	System	06 Sep 2020 21:01:39

FDA-CBER-2022-1614-6051151

US3542168
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 26 Nov 2020 09:37:10
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-06T17:01:35', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '21edc182-8f82-46d3-96f5-025d9c6ec6d4'	System	06 Sep 2020 21:01:39
User entered '06 Sep 2020 17:01'	System	06 Sep 2020 21:01:39

US3542168
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 26 Nov 2020 09:37:10
PC Open Date & Time

Audit	User	Time (GMT)
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051153

US3542168
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 26 Nov 2020 09:37:10
PC Close Date & Time

Audit	User	Time (GMT)
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051154

US3542168
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 26 Nov 2020 09:37:10
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 4'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051155

US3542168
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 26 Nov 2020 09:37:10
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-07T13:21:15', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'ba626aa1-3637-48b5-8c33-545ef91b7de8'	System	07 Sep 2020 17:21:36
User entered 'None (1)'	System	07 Sep 2020 17:21:36

FDA-CBER-2022-1614-6051156

US3542168
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 26 Nov 2020 09:37:10
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-07T13:21:19', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'ba626aa1-3637-48b5-8c33-545ef91b7de8'	System	07 Sep 2020 17:21:36
User entered 'No (N)'	System	07 Sep 2020 17:21:36

FDA-CBER-2022-1614-6051157

US3542168
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 26 Nov 2020 09:37:10
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-07T13:21:22', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'ba626aa1-3637-48b5-8c33-545ef91b7de8'	System	07 Sep 2020 17:21:36
User entered 'No (N)'	System	07 Sep 2020 17:21:36

US3542168
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 26 Nov 2020 09:37:10
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-07T13:21:27', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'ba626aa1-3637-48b5-8c33-545ef91b7de8'	System	07 Sep 2020 17:21:36
User entered 'None (1)'	System	07 Sep 2020 17:21:36

FDA-CBER-2022-1614-6051159

US3542168
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 26 Nov 2020 09:37:10
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-07T13:21:31', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'ba626aa1-3637-48b5-8c33-545ef91b7de8'	System	07 Sep 2020 17:21:36
User entered '07 Sep 2020 13:21'	System	07 Sep 2020 17:21:36

FDA-CBER-2022-1614-6051160

US3542168
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 26 Nov 2020 09:37:10
PC Open Date & Time

Audit	User	Time (GMT)
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051161

US3542168
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 26 Nov 2020 09:37:10
PC Close Date & Time

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051162

US3542168
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 26 Nov 2020 09:37:10
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 5'	System	04 Sep 2020 20:20:50

US3542168
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 26 Nov 2020 09:37:10
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-08T13:25:54', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '7cae1991-bef9-4f23-8fb0-f8acbe01746a'	System	08 Sep 2020 17:26:10
User entered 'None (1)'	System	08 Sep 2020 17:26:10

FDA-CBER-2022-1614-6051164

US3542168
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 26 Nov 2020 09:37:10
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-08T13:25:57', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '7cae1991-bef9-4f23-8fb0-f8acbe01746a'	System	08 Sep 2020 17:26:10
User entered 'No (N)'	System	08 Sep 2020 17:26:10

US3542168
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 26 Nov 2020 09:37:10
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-08T13:26:00', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '7cae1991-bef9-4f23-8fb0-f8acbe01746a'	System	08 Sep 2020 17:26:10
User entered 'No (N)'	System	08 Sep 2020 17:26:10

US3542168
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 26 Nov 2020 09:37:10
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-08T13:26:03', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '7cae1991-bef9-4f23-8fb0-f8acbe01746a'	System	08 Sep 2020 17:26:10
User entered 'None (1)'	System	08 Sep 2020 17:26:10

US3542168
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 26 Nov 2020 09:37:10
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-08T13:26:06', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '7cae1991-bef9-4f23-8fb0-f8acbe01746a'	System	08 Sep 2020 17:26:10
User entered '08 Sep 2020 13:26'	System	08 Sep 2020 17:26:10

FDA-CBER-2022-1614-6051168

US3542168
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 26 Nov 2020 09:37:10
PC Open Date & Time

Audit	User	Time (GMT)
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051169

US3542168
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 26 Nov 2020 09:37:10
PC Close Date & Time

Audit	User	Time (GMT)
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051170

US3542168
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 26 Nov 2020 09:37:10
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 6'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051171

US3542168
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 26 Nov 2020 09:37:10
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-09T12:08:09', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '05062454-3ae4-4199-96b8-fa3444f26931'	System	09 Sep 2020 16:08:29
User entered 'None (1)'	System	09 Sep 2020 16:08:29

FDA-CBER-2022-1614-6051172

US3542168
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 26 Nov 2020 09:37:10
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-09T12:08:13', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '05062454-3ae4-4199-96b8-fa3444f26931'	System	09 Sep 2020 16:08:29
User entered 'No (N)'	System	09 Sep 2020 16:08:29

US3542168
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 26 Nov 2020 09:37:10
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-09T12:08:16', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '05062454-3ae4-4199-96b8-fa3444f26931'	System	09 Sep 2020 16:08:29
User entered 'No (N)'	System	09 Sep 2020 16:08:29

US3542168
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 26 Nov 2020 09:37:10
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-09T12:08:19', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '05062454-3ae4-4199-96b8-fa3444f26931'	System	09 Sep 2020 16:08:29
User entered 'None (1)'	System	09 Sep 2020 16:08:29

FDA-CBER-2022-1614-6051175

US3542168
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 26 Nov 2020 09:37:10
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-09T12:08:23', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '05062454-3ae4-4199-96b8-fa3444f26931'	System	09 Sep 2020 16:08:29
User entered '09 Sep 2020 12:08'	System	09 Sep 2020 16:08:29

FDA-CBER-2022-1614-6051176

US3542168
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 26 Nov 2020 09:37:10
PC Open Date & Time

Audit	User	Time (GMT)
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051177

US3542168
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 26 Nov 2020 09:37:10
PC Close Date & Time

Audit	User	Time (GMT)
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051178

US3542168
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 26 Nov 2020 09:37:10
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 7'	System	04 Sep 2020 20:20:50

US3542168
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 26 Nov 2020 09:37:10
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-10T20:30:45', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '9d35d241-deac-4537-b234-a4f923f1cf85'	System	11 Sep 2020 00:31:08
User entered 'None (1)'	System	11 Sep 2020 00:31:08

FDA-CBER-2022-1614-6051180

US3542168
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 26 Nov 2020 09:37:10
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-10T20:30:54', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '9d35d241-deac-4537-b234-a4f923f1cf85'	System	11 Sep 2020 00:31:08
User entered 'No (N)'	System	11 Sep 2020 00:31:08

US3542168
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 26 Nov 2020 09:37:10
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-10T20:30:58', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '9d35d241-deac-4537-b234-a4f923f1cf85'	System	11 Sep 2020 00:31:08
User entered 'No (N)'	System	11 Sep 2020 00:31:08

US3542168
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 26 Nov 2020 09:37:10
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-10T20:31:01', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '9d35d241-deac-4537-b234-a4f923f1cf85'	System	11 Sep 2020 00:31:08
User entered 'None (1)'	System	11 Sep 2020 00:31:08

US3542168
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 26 Nov 2020 09:37:10
PC Time Stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-10T20:31:04', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '9d35d241-deac-4537-b234-a4f923f1cf85'	System	11 Sep 2020 00:31:08
User entered '10 Sep 2020 20:31'	System	11 Sep 2020 00:31:08

US3542168
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 26 Nov 2020 09:37:10
PC Open Date & Time

Audit	User	Time (GMT)
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051185

US3542168
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 26 Nov 2020 09:37:10
PC Close Date & Time

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051186

US3542168
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 26 Nov 2020 09:37:10
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051187

US3542168
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 26 Nov 2020 09:37:10
HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-04T16:54:47', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '2924b2c0-a0ee-4bcc-beec-8eaf08901591'	System	04 Sep 2020 20:55:10
User entered 'None (0)'	System	04 Sep 2020 20:55:10

US3542168
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 26 Nov 2020 09:37:10
FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-04T16:54:53', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '2924b2c0-a0ee-4bcc-beec-8eaf08901591'	System	04 Sep 2020 20:55:10
User entered 'None (0)'	System	04 Sep 2020 20:55:10

FDA-CBER-2022-1614-6051189

US3542168
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 26 Nov 2020 09:37:10
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-04T16:54:58', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '2924b2c0-a0ee-4bcc-beec-8eaf08901591'	System	04 Sep 2020 20:55:10
User entered 'None (0)'	System	04 Sep 2020 20:55:10

FDA-CBER-2022-1614-6051190

US3542168
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 26 Nov 2020 09:37:10
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-04T16:54:10', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '2924b2c0-a0ee-4bcc-beec-8eaf08901591'	System	04 Sep 2020 20:55:10
User entered 'None (0)'	System	04 Sep 2020 20:55:10

US3542168
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 26 Nov 2020 09:37:10
NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-04T16:53:57', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '2924b2c0-a0ee-4bcc-beec-8eaf08901591'	System	04 Sep 2020 20:55:10
User entered 'None (0)'	System	04 Sep 2020 20:55:10

US3542168
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 26 Nov 2020 09:37:10
CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-04T16:54:14', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '2924b2c0-a0ee-4bcc-beec-8eaf08901591'	System	04 Sep 2020 20:55:10
User entered 'None (0)'	System	04 Sep 2020 20:55:10

US3542168
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 26 Nov 2020 09:37:10
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-04T16:54:27', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '2924b2c0-a0ee-4bcc-beec-8eaf08901591'	System	04 Sep 2020 20:55:10
User entered 'No (N)'	System	04 Sep 2020 20:55:10

US3542168
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 26 Nov 2020 09:37:10
PC Time stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-04T16:55:07', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '2924b2c0-a0ee-4bcc-beec-8eaf08901591'	System	04 Sep 2020 20:55:10
User entered '04 Sep 2020 16:55'	System	04 Sep 2020 20:55:10

FDA-CBER-2022-1614-6051195

US3542168
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 26 Nov 2020 09:37:10
PC Open Date & Time

Audit	User	Time (GMT)
User entered '04 Sep 2020 16:38'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051196

US3542168
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 26 Nov 2020 09:37:10
PC Close Date & Time

Audit	User	Time (GMT)
User entered '04 Sep 2020 19:08'	System	04 Sep 2020 20:20:50

US3542168
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 26 Nov 2020 09:37:10
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051198

US3542168
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 26 Nov 2020 09:37:10
HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-04T20:13:05', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '4b398103-bf77-4092-8805-146974e3d24f'	System	05 Sep 2020 00:13:46
User entered 'None (0)'	System	05 Sep 2020 00:13:46

FDA-CBER-2022-1614-6051199

US3542168
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 26 Nov 2020 09:37:10
FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-04T20:13:09', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '4b398103-bf77-4092-8805-146974e3d24f'	System	05 Sep 2020 00:13:46
User entered 'None (0)'	System	05 Sep 2020 00:13:46

US3542168
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 26 Nov 2020 09:37:10
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-04T20:13:13', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '4b398103-bf77-4092-8805-146974e3d24f'	System	05 Sep 2020 00:13:46
User entered 'None (0)'	System	05 Sep 2020 00:13:46

FDA-CBER-2022-1614-6051201

US3542168
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 26 Nov 2020 09:37:10
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-04T20:13:16', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '4b398103-bf77-4092-8805-146974e3d24f'	System	05 Sep 2020 00:13:46
User entered 'None (0)'	System	05 Sep 2020 00:13:46

US3542168
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 26 Nov 2020 09:37:10
NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-04T20:13:21', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '4b398103-bf77-4092-8805-146974e3d24f'	System	05 Sep 2020 00:13:46
User entered 'None (0)'	System	05 Sep 2020 00:13:46

US3542168
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 26 Nov 2020 09:37:10
CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-04T20:13:25', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '4b398103-bf77-4092-8805-146974e3d24f'	System	05 Sep 2020 00:13:46
User entered 'None (0)'	System	05 Sep 2020 00:13:46

US3542168
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 26 Nov 2020 09:37:10
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-04T20:13:36', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '4b398103-bf77-4092-8805-146974e3d24f'	System	05 Sep 2020 00:13:46
User entered 'No (N)'	System	05 Sep 2020 00:13:46

FDA-CBER-2022-1614-6051205

US3542168
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 26 Nov 2020 09:37:10
PC Time stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-04T20:13:41', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '4b398103-bf77-4092-8805-146974e3d24f'	System	05 Sep 2020 00:13:46
User entered '04 Sep 2020 20:13'	System	05 Sep 2020 00:13:46

FDA-CBER-2022-1614-6051206

US3542168
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 26 Nov 2020 09:37:10
PC Open Date & Time

Audit	User	Time (GMT)
User entered '04 Sep 2020 20:03'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051207

US3542168
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 26 Nov 2020 09:37:10
PC Close Date & Time

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051208

US3542168
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 26 Nov 2020 09:37:10
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 2'	System	04 Sep 2020 20:20:50

US3542168
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 26 Nov 2020 09:37:10
HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-05T13:03:42', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'f53cd8bf-54fa-4105-81e4-a84542a723b3'	System	05 Sep 2020 17:04:12
User entered 'None (0)'	System	05 Sep 2020 17:04:12

FDA-CBER-2022-1614-6051210

US3542168
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 26 Nov 2020 09:37:10
FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-05T13:03:45', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'f53cd8bf-54fa-4105-81e4-a84542a723b3'	System	05 Sep 2020 17:04:12
User entered 'None (0)'	System	05 Sep 2020 17:04:12

FDA-CBER-2022-1614-6051211

US3542168
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 26 Nov 2020 09:37:10
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-05T13:03:48', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'f53cd8bf-54fa-4105-81e4-a84542a723b3'	System	05 Sep 2020 17:04:12
User entered 'None (0)'	System	05 Sep 2020 17:04:12

US3542168
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 26 Nov 2020 09:37:10
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-05T13:03:52', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'f53cd8bf-54fa-4105-81e4-a84542a723b3'	System	05 Sep 2020 17:04:12
User entered 'None (0)'	System	05 Sep 2020 17:04:12

FDA-CBER-2022-1614-6051213

US3542168
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 26 Nov 2020 09:37:10
NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-05T13:03:55', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'f53cd8bf-54fa-4105-81e4-a84542a723b3'	System	05 Sep 2020 17:04:12
User entered 'None (0)'	System	05 Sep 2020 17:04:12

FDA-CBER-2022-1614-6051214

US3542168
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 26 Nov 2020 09:37:10
CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-05T13:03:57', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'f53cd8bf-54fa-4105-81e4-a84542a723b3'	System	05 Sep 2020 17:04:12
User entered 'None (0)'	System	05 Sep 2020 17:04:12

FDA-CBER-2022-1614-6051215

US3542168
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 26 Nov 2020 09:37:10
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-05T13:04:05', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'f53cd8bf-54fa-4105-81e4-a84542a723b3'	System	05 Sep 2020 17:04:12
User entered 'No (N)'	System	05 Sep 2020 17:04:12

FDA-CBER-2022-1614-6051216

US3542168
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 26 Nov 2020 09:37:10
PC Time stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-05T13:04:09', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'f53cd8bf-54fa-4105-81e4-a84542a723b3'	System	05 Sep 2020 17:04:12
User entered '05 Sep 2020 13:04'	System	05 Sep 2020 17:04:12

FDA-CBER-2022-1614-6051217

US3542168
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 26 Nov 2020 09:37:10
PC Open Date & Time

Audit	User	Time (GMT)
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051218

US3542168
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 26 Nov 2020 09:37:10
PC Close Date & Time

Audit	User	Time (GMT)
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051219

US3542168
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 26 Nov 2020 09:37:10
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 3'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051220

US3542168
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 26 Nov 2020 09:37:10
HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-06T17:01:50', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '94948479-deed-4432-bd10-3853e06feb4e'	System	06 Sep 2020 21:02:32
User entered 'None (0)'	System	06 Sep 2020 21:02:32

FDA-CBER-2022-1614-6051221

US3542168
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 26 Nov 2020 09:37:10
FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-06T17:01:59', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '94948479-deed-4432-bd10-3853e06feb4e'	System	06 Sep 2020 21:02:32
User entered 'None (0)'	System	06 Sep 2020 21:02:32

US3542168
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 26 Nov 2020 09:37:10
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-06T17:02:03', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '94948479-deed-4432-bd10-3853e06feb4e'	System	06 Sep 2020 21:02:32
User entered 'None (0)'	System	06 Sep 2020 21:02:32

FDA-CBER-2022-1614-6051223

US3542168
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 26 Nov 2020 09:37:10
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-06T17:02:10', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '94948479-deed-4432-bd10-3853e06feb4e'	System	06 Sep 2020 21:02:32
User entered 'None (0)'	System	06 Sep 2020 21:02:32

FDA-CBER-2022-1614-6051224

US3542168
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 26 Nov 2020 09:37:10
NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-06T17:02:13', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '94948479-deed-4432-bd10-3853e06feb4e'	System	06 Sep 2020 21:02:32
User entered 'None (0)'	System	06 Sep 2020 21:02:32

FDA-CBER-2022-1614-6051225

US3542168
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 26 Nov 2020 09:37:10
CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-06T17:02:16', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '94948479-deed-4432-bd10-3853e06feb4e'	System	06 Sep 2020 21:02:32
User entered 'None (0)'	System	06 Sep 2020 21:02:32

US3542168
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 26 Nov 2020 09:37:10
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-06T17:02:23', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '94948479-deed-4432-bd10-3853e06feb4e'	System	06 Sep 2020 21:02:32
User entered 'No (N)'	System	06 Sep 2020 21:02:32

FDA-CBER-2022-1614-6051227

US3542168
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 26 Nov 2020 09:37:10
PC Time stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-06T17:02:27', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '94948479-deed-4432-bd10-3853e06feb4e'	System	06 Sep 2020 21:02:32
User entered '06 Sep 2020 17:02'	System	06 Sep 2020 21:02:32

US3542168
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 26 Nov 2020 09:37:10
PC Open Date & Time

Audit	User	Time (GMT)
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051229

US3542168
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 26 Nov 2020 09:37:10
PC Close Date & Time

Audit	User	Time (GMT)
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051230

US3542168
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 26 Nov 2020 09:37:10
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 4'	System	04 Sep 2020 20:20:50

US3542168
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 26 Nov 2020 09:37:10
HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-07T13:21:37', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '7778134d-1db3-4737-b3f8-0d288edfb992'	System	07 Sep 2020 17:22:05
User entered 'None (0)'	System	07 Sep 2020 17:22:05

US3542168
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 26 Nov 2020 09:37:10
FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-07T13:21:40', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '7778134d-1db3-4737-b3f8-0d288edfb992'	System	07 Sep 2020 17:22:05
User entered 'None (0)'	System	07 Sep 2020 17:22:05

US3542168
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 26 Nov 2020 09:37:10
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-07T13:21:43', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '7778134d-1db3-4737-b3f8-0d288edfb992'	System	07 Sep 2020 17:22:05
User entered 'None (0)'	System	07 Sep 2020 17:22:05

US3542168
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 26 Nov 2020 09:37:10
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-07T13:21:46', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '7778134d-1db3-4737-b3f8-0d288edfb992'	System	07 Sep 2020 17:22:05
User entered 'None (0)'	System	07 Sep 2020 17:22:05

FDA-CBER-2022-1614-6051235

US3542168
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 26 Nov 2020 09:37:10
NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-07T13:21:48', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '7778134d-1db3-4737-b3f8-0d288edfb992'	System	07 Sep 2020 17:22:05
User entered 'None (0)'	System	07 Sep 2020 17:22:05

US3542168
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 26 Nov 2020 09:37:10
CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-07T13:21:51', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '7778134d-1db3-4737-b3f8-0d288edfb992'	System	07 Sep 2020 17:22:05
User entered 'None (0)'	System	07 Sep 2020 17:22:05

US3542168
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 26 Nov 2020 09:37:10
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-07T13:21:55', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '7778134d-1db3-4737-b3f8-0d288edfb992'	System	07 Sep 2020 17:22:05
User entered 'No (N)'	System	07 Sep 2020 17:22:05

FDA-CBER-2022-1614-6051238

US3542168
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 26 Nov 2020 09:37:10
PC Time stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-07T13:22:02', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '7778134d-1db3-4737-b3f8-0d288edfb992'	System	07 Sep 2020 17:22:05
User entered '07 Sep 2020 13:22'	System	07 Sep 2020 17:22:05

US3542168
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 26 Nov 2020 09:37:10
PC Open Date & Time

Audit	User	Time (GMT)
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051240

US3542168
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 26 Nov 2020 09:37:10
PC Close Date & Time

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051241

US3542168
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 26 Nov 2020 09:37:10
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 5'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051242

US3542168
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 26 Nov 2020 09:37:10
HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-08T13:26:12', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'd8936f63-ed40-4ca3-9f24-89781ed49892'	System	08 Sep 2020 17:26:33
User entered 'None (0)'	System	08 Sep 2020 17:26:33

US3542168
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 26 Nov 2020 09:37:10
FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-08T13:26:14', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'd8936f63-ed40-4ca3-9f24-89781ed49892'	System	08 Sep 2020 17:26:33
User entered 'None (0)'	System	08 Sep 2020 17:26:33

FDA-CBER-2022-1614-6051244

US3542168
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 26 Nov 2020 09:37:10
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-08T13:26:16', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'd8936f63-ed40-4ca3-9f24-89781ed49892'	System	08 Sep 2020 17:26:33
User entered 'None (0)'	System	08 Sep 2020 17:26:33

FDA-CBER-2022-1614-6051245

US3542168
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 26 Nov 2020 09:37:10
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-08T13:26:18', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'd8936f63-ed40-4ca3-9f24-89781ed49892'	System	08 Sep 2020 17:26:33
User entered 'None (0)'	System	08 Sep 2020 17:26:33

FDA-CBER-2022-1614-6051246

US3542168
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 26 Nov 2020 09:37:10
NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-08T13:26:20', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'd8936f63-ed40-4ca3-9f24-89781ed49892'	System	08 Sep 2020 17:26:33
User entered 'None (0)'	System	08 Sep 2020 17:26:33

US3542168
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 26 Nov 2020 09:37:10
CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-08T13:26:23', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'd8936f63-ed40-4ca3-9f24-89781ed49892'	System	08 Sep 2020 17:26:33
User entered 'None (0)'	System	08 Sep 2020 17:26:33

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:37:10

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-08T13:26:26', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'd8936f63-ed40-4ca3-9f24-89781ed49892'	System	08 Sep 2020 17:26:33
User entered 'No (N)'	System	08 Sep 2020 17:26:33

US3542168
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 26 Nov 2020 09:37:10
PC Time stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-08T13:26:29', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'd8936f63-ed40-4ca3-9f24-89781ed49892'	System	08 Sep 2020 17:26:33
User entered '08 Sep 2020 13:26'	System	08 Sep 2020 17:26:33

FDA-CBER-2022-1614-6051250

US3542168
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 26 Nov 2020 09:37:10
PC Open Date & Time

Audit	User	Time (GMT)
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051251

US3542168
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 26 Nov 2020 09:37:10
PC Close Date & Time

Audit	User	Time (GMT)
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051252

US3542168
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 26 Nov 2020 09:37:10
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 6'	System	04 Sep 2020 20:20:50

US3542168
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 26 Nov 2020 09:37:10
HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-09T12:08:28', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'b18e4a1b-08e3-4440-9ece-5dbe5196f8d5'	System	09 Sep 2020 16:08:51
User entered 'None (0)'	System	09 Sep 2020 16:08:51

US3542168
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 26 Nov 2020 09:37:10
FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-09T12:08:30', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'b18e4a1b-08e3-4440-9ece-5dbe5196f8d5'	System	09 Sep 2020 16:08:51
User entered 'None (0)'	System	09 Sep 2020 16:08:51

US3542168
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 26 Nov 2020 09:37:10
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-09T12:08:33', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'b18e4a1b-08e3-4440-9ece-5dbe5196f8d5'	System	09 Sep 2020 16:08:51
User entered 'None (0)'	System	09 Sep 2020 16:08:51

US3542168
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 26 Nov 2020 09:37:10
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-09T12:08:35', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'b18e4a1b-08e3-4440-9ece-5dbe5196f8d5'	System	09 Sep 2020 16:08:51
User entered 'None (0)'	System	09 Sep 2020 16:08:51

US3542168
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 26 Nov 2020 09:37:10
NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-09T12:08:38', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'b18e4a1b-08e3-4440-9ece-5dbe5196f8d5'	System	09 Sep 2020 16:08:51
User entered 'None (0)'	System	09 Sep 2020 16:08:51

US3542168
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 26 Nov 2020 09:37:10
CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-09T12:08:40', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'b18e4a1b-08e3-4440-9ece-5dbe5196f8d5'	System	09 Sep 2020 16:08:51
User entered 'None (0)'	System	09 Sep 2020 16:08:51

US3542168
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 26 Nov 2020 09:37:10
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-09T12:08:43', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'b18e4a1b-08e3-4440-9ece-5dbe5196f8d5'	System	09 Sep 2020 16:08:51
User entered 'No (N)'	System	09 Sep 2020 16:08:51

US3542168
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 26 Nov 2020 09:37:10
PC Time stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-09T12:08:46', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: 'b18e4a1b-08e3-4440-9ece-5dbe5196f8d5'	System	09 Sep 2020 16:08:51
User entered '09 Sep 2020 12:08'	System	09 Sep 2020 16:08:51

FDA-CBER-2022-1614-6051261

US3542168
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 26 Nov 2020 09:37:10
PC Open Date & Time

Audit	User	Time (GMT)
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051262

US3542168
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 26 Nov 2020 09:37:10
PC Close Date & Time

Audit	User	Time (GMT)
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051263

US3542168
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 26 Nov 2020 09:37:10
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 7'	System	04 Sep 2020 20:20:50

US3542168
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 26 Nov 2020 09:37:10
HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-10T20:31:10', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '5dca829f-f712-4509-a68f-240fe108fc69'	System	11 Sep 2020 00:31:31
User entered 'None (0)'	System	11 Sep 2020 00:31:31

FDA-CBER-2022-1614-6051265

US3542168
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 26 Nov 2020 09:37:10
FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-10T20:31:14', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '5dca829f-f712-4509-a68f-240fe108fc69'	System	11 Sep 2020 00:31:31
User entered 'None (0)'	System	11 Sep 2020 00:31:31

US3542168
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 26 Nov 2020 09:37:10
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-10T20:31:16', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '5dca829f-f712-4509-a68f-240fe108fc69'	System	11 Sep 2020 00:31:31
User entered 'None (0)'	System	11 Sep 2020 00:31:31

FDA-CBER-2022-1614-6051267

US3542168
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 26 Nov 2020 09:37:10
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-10T20:31:18', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '5dca829f-f712-4509-a68f-240fe108fc69'	System	11 Sep 2020 00:31:31
User entered 'None (0)'	System	11 Sep 2020 00:31:31

FDA-CBER-2022-1614-6051268

US3542168
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 26 Nov 2020 09:37:10
NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-10T20:31:21', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '5dca829f-f712-4509-a68f-240fe108fc69'	System	11 Sep 2020 00:31:31
User entered 'None (0)'	System	11 Sep 2020 00:31:31

FDA-CBER-2022-1614-6051269

US3542168
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 26 Nov 2020 09:37:10
CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-10T20:31:23', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '5dca829f-f712-4509-a68f-240fe108fc69'	System	11 Sep 2020 00:31:31
User entered 'None (0)'	System	11 Sep 2020 00:31:31

US3542168

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:37:10

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-10T20:31:26', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '5dca829f-f712-4509-a68f-240fe108fc69'	System	11 Sep 2020 00:31:31
User entered 'No (N)'	System	11 Sep 2020 00:31:31

US3542168
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 26 Nov 2020 09:37:10
PC Time stamp

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5f146c42a7dd617b)', Time: '2020-09-10T20:31:29', User OID: 'PatientReportedOutcome (US3542168)', ODM File OID: '5dca829f-f712-4509-a68f-240fe108fc69'	System	11 Sep 2020 00:31:31
User entered '10 Sep 2020 20:31'	System	11 Sep 2020 00:31:31

US3542168
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 26 Nov 2020 09:37:10
PC Open Date & Time

Audit	User	Time (GMT)
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051273

US3542168
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 26 Nov 2020 09:37:10
PC Close Date & Time

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 20:20:50

US3542168
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 26 Nov 2020 09:37:10
Was Contact Attempted?

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	17 Sep 2020 04:28:58
User entered 'Yes (Y)'	Madhu Balachandran (b) (4)	16 Sep 2020 18:42:25

FDA-CBER-2022-1614-6051275

US3542168
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 26 Nov 2020 09:37:10
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	17 Sep 2020 04:28:58
User entered '14 Sep 2020'	Madhu Balachandran (b) (4)	16 Sep 2020 18:42:25

FDA-CBER-2022-1614-6051276

US3542168
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 26 Nov 2020 09:37:10
Please select one status for the follow-up contact

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	17 Sep 2020 04:28:58
User entered 'Contact Not Made (CONTACT NOT MADE)'	Madhu Balachandran (b) (4)	16 Sep 2020 18:42:25

FDA-CBER-2022-1614-6051277

US3542168
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 26 Nov 2020 09:37:10
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	17 Sep 2020 04:28:58
User entered 'Called 5 times in 2 days. Unable to leave voicemail.'	Madhu Balachandran (b) (4)	16 Sep 2020 18:42:25

FDA-CBER-2022-1614-6051278

US3542168
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 26 Nov 2020 09:37:10
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	17 Sep 2020 04:28:58
User entered 'Yes (Y)'	Madhu Balachandran (b) (4)	16 Sep 2020 18:45:29

FDA-CBER-2022-1614-6051279

US3542168
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 26 Nov 2020 09:37:10
Continuing Flag

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 18:45:29

FDA-CBER-2022-1614-6051280

US3542168
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 26 Nov 2020 09:37:10
Was Contact Attempted?

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:24:13
User entered 'Yes (Y)'	Erika Faust (b) (4) (b) (4)	02 Nov 2020 18:36:13

FDA-CBER-2022-1614-6051281

US3542168
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 26 Nov 2020 09:37:10
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:24:13
User entered '18 Sep 2020'	Erika Faust (b) (4) (b) (4)	02 Nov 2020 18:36:13

FDA-CBER-2022-1614-6051282

US3542168
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 26 Nov 2020 09:37:10
Please select one status for the follow-up contact

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:24:13
User entered 'Contact Made (CONTACT MADE)'	Erika Faust (b) (4) (b) (4)	02 Nov 2020 18:36:13

FDA-CBER-2022-1614-6051283

US3542168
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 26 Nov 2020 09:37:10
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:24:13
User entered empty.	Erika Faust (b) (4) (b) (4)	02 Nov 2020 18:36:13

FDA-CBER-2022-1614-6051284

US3542168
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 26 Nov 2020 09:37:10
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered 'Yes (Y)'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 15:05:56

FDA-CBER-2022-1614-6051285

US3542168
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 26 Nov 2020 09:37:10
Continuing Flag

Audit	User	Time (GMT)
User entered '1'	System	30 Sep 2020 15:05:56

FDA-CBER-2022-1614-6051286

US3542168
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 26 Nov 2020 09:37:10
Was Contact Attempted?

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered 'Yes (Y)'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 15:06:09

FDA-CBER-2022-1614-6051287

US3542168
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 26 Nov 2020 09:37:10
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered '25 Sep 2020'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 15:06:09

FDA-CBER-2022-1614-6051288

US3542168
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 26 Nov 2020 09:37:10
Please select one status for the follow-up contact

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered 'Contact Made (CONTACT MADE)'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 15:06:09

FDA-CBER-2022-1614-6051289

US3542168
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 26 Nov 2020 09:37:10
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered empty.	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 15:06:09

FDA-CBER-2022-1614-6051290

US3542168
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 26 Nov 2020 09:37:10
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Oct 2020 04:17:01
Signature has been broken.	Erika Faust (b) (4) (b) (4)	09 Oct 2020 15:36:51
User entered 'Yes (Y)' reason for change: Data Entry Error	Erika Faust (b) (4) (b) (4)	09 Oct 2020 15:36:51
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered 'No (N)'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 15:06:14

FDA-CBER-2022-1614-6051291

US3542168
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 26 Nov 2020 09:37:10
Continuing Flag

Audit	User	Time (GMT)
User entered '1'	System	09 Oct 2020 15:36:51
User entered empty.	System	30 Sep 2020 15:06:14

FDA-CBER-2022-1614-6051292

US3542168
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 26 Nov 2020 09:37:10
Was this visit performed?

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Oct 2020 04:17:01
User entered 'Yes (Y)'	Erika Faust (b) (4) (b) (4)	09 Oct 2020 15:37:13

FDA-CBER-2022-1614-6051293

US3542168
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 26 Nov 2020 09:37:10
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Oct 2020 04:17:01
User entered '8 Oct 2020'	Erika Faust (b) (4) (b) (4)	09 Oct 2020 15:37:13

FDA-CBER-2022-1614-6051294

US3542168
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 26 Nov 2020 09:37:10
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Oct 2020 04:17:01
User entered 'Clinic (Clinic)'	Erika Faust (b) (4) (b) (4)	09 Oct 2020 15:37:13

FDA-CBER-2022-1614-6051295

US3542168
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 26 Nov 2020 09:37:10
Folder OID

Audit	User	Time (GMT)
User entered 'VISIT2'	System	09 Oct 2020 15:37:13

FDA-CBER-2022-1614-6051296

US3542168
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 09:37:10
Timepoint

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Erika Faust (b) (4) (b) (4)	09 Oct 2020 17:48:19

FDA-CBER-2022-1614-6051297

US3542168
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 09:37:10
Were vital signs assessed?

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Oct 2020 04:17:01
User entered 'Yes (Y)'	Erika Faust (b) (4) (b) (4)	09 Oct 2020 17:48:19

FDA-CBER-2022-1614-6051298

US3542168
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 09:37:10
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Oct 2020 04:17:01
User entered '8 Oct 2020'	Erika Faust (b) (4) (b) (4)	09 Oct 2020 17:48:19

FDA-CBER-2022-1614-6051299

US3542168
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 09:37:10
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Oct 2020 04:17:01
User entered '10:47'	Erika Faust (b) (4) (b) (4)	09 Oct 2020 17:48:19

FDA-CBER-2022-1614-6051300

US3542168
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 09:37:10
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
User entered '8 Oct 2020 10:47'	System	09 Oct 2020 17:48:19

FDA-CBER-2022-1614-6051301

US3542168
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 09:37:10
Temperature *(xxx.x)*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Oct 2020 04:17:01
User entered '98.4' F	Erika Faust (b) (4) (b) (4)	09 Oct 2020 17:48:19

FDA-CBER-2022-1614-6051302

US3542168
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 09:37:10
Route of measurement

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Oct 2020 04:17:01
User entered 'Oral (Oral)'	Erika Faust (b) (4) (b) (4)	09 Oct 2020 17:48:19

FDA-CBER-2022-1614-6051303

US3542168
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 09:37:10
If Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Oct 2020 04:17:01
User entered empty.	Erika Faust (b) (4) (b) (4)	09 Oct 2020 17:48:19

FDA-CBER-2022-1614-6051304

US3542168
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 09:37:10
Pulse *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Oct 2020 04:17:01
User entered '73'	Erika Faust (b) (4) (b) (4)	09 Oct 2020 17:48:19

FDA-CBER-2022-1614-6051305

US3542168
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 09:37:10
Pulse units

Audit	User	Time (GMT)
User entered 'bpm'	System	09 Oct 2020 17:48:19

FDA-CBER-2022-1614-6051306

US3542168
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 09:37:10
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Oct 2020 04:17:01
User entered '16'	Erika Faust (b) (4) (b) (4)	09 Oct 2020 17:48:19

FDA-CBER-2022-1614-6051307

US3542168
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 09:37:10
Respiratory Rate units

Audit	User	Time (GMT)
User entered 'breaths/min'	System	09 Oct 2020 17:48:19

FDA-CBER-2022-1614-6051308

US3542168
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 09:37:10
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Oct 2020 04:17:01
User entered '125'	Erika Faust (b) (4) (b) (4)	09 Oct 2020 17:48:19

FDA-CBER-2022-1614-6051309

US3542168
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 09:37:10
Systolic Blood Pressure units

Audit	User	Time (GMT)
User entered 'mmHg'	System	09 Oct 2020 17:48:19

FDA-CBER-2022-1614-6051310

US3542168
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 09:37:10
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Oct 2020 04:17:01
User entered '92'	Erika Faust (b) (4) (b) (4)	09 Oct 2020 17:48:19

FDA-CBER-2022-1614-6051311

US3542168
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 26 Nov 2020 09:37:10
Diastolic Blood Pressure units

Audit	User	Time (GMT)
User entered 'mmHg'	System	09 Oct 2020 17:48:19

FDA-CBER-2022-1614-6051312

US3542168
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 09:37:10
Timepoint

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Erika Faust (b) (4) (b) (4)	09 Oct 2020 17:48:19

FDA-CBER-2022-1614-6051313

US3542168
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 09:37:10
Were vital signs assessed?

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Oct 2020 04:17:01
User entered 'No (N)'	Erika Faust (b) (4) (b) (4)	09 Oct 2020 17:48:19

FDA-CBER-2022-1614-6051314

US3542168
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 09:37:10
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Oct 2020 04:17:01
User entered empty.	Erika Faust (b) (4) (b) (4)	09 Oct 2020 17:48:19

FDA-CBER-2022-1614-6051315

US3542168
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 09:37:10
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Oct 2020 04:17:01
User entered empty.	Erika Faust (b) (4) (b) (4)	09 Oct 2020 17:48:19

FDA-CBER-2022-1614-6051316

US3542168
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 09:37:10
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 17:48:19

FDA-CBER-2022-1614-6051317

US3542168
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 09:37:10
Temperature *(xxx.x)*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Oct 2020 04:17:01
User entered empty.	Erika Faust (b) (4) (b) (4)	09 Oct 2020 17:48:19

FDA-CBER-2022-1614-6051318

US3542168
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 09:37:10
Route of measurement

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Oct 2020 04:17:01
User entered empty.	Erika Faust (b) (4) (b) (4)	09 Oct 2020 17:48:19

FDA-CBER-2022-1614-6051319

US3542168
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 09:37:10
If Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Oct 2020 04:17:01
User entered empty.	Erika Faust (b) (4) (b) (4)	09 Oct 2020 17:48:19

FDA-CBER-2022-1614-6051320

US3542168
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 09:37:10
Pulse *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Oct 2020 04:17:01
User entered empty.	Erika Faust (b) (4) (b) (4)	09 Oct 2020 17:48:19

FDA-CBER-2022-1614-6051321

US3542168
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 09:37:10
Pulse units

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 17:48:19

FDA-CBER-2022-1614-6051322

US3542168
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 09:37:10
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Oct 2020 04:17:01
User entered empty.	Erika Faust (b) (4) (b) (4)	09 Oct 2020 17:48:19

FDA-CBER-2022-1614-6051323

US3542168
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 09:37:10
Respiratory Rate units

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 17:48:19

FDA-CBER-2022-1614-6051324

US3542168
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 09:37:10
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Oct 2020 04:17:01
User entered empty.	Erika Faust (b) (4) (b) (4)	09 Oct 2020 17:48:19

FDA-CBER-2022-1614-6051325

US3542168
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 09:37:10
Systolic Blood Pressure units

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 17:48:19

FDA-CBER-2022-1614-6051326

US3542168
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 09:37:10
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Oct 2020 04:17:01
User entered empty.	Erika Faust (b) (4) (b) (4)	09 Oct 2020 17:48:19

FDA-CBER-2022-1614-6051327

US3542168
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 26 Nov 2020 09:37:10
Diastolic Blood Pressure units

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 17:48:19

FDA-CBER-2022-1614-6051328

US3542168
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Generated On: 26 Nov 2020 09:37:10
Was the physical examination performed?

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Oct 2020 04:17:01
User entered 'Yes (Y)'	Erika Faust (b) (4) (b) (4)	09 Oct 2020 15:37:21

FDA-CBER-2022-1614-6051329

US3542168
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Generated On: 26 Nov 2020 09:37:10
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Oct 2020 04:17:01
User entered '8 Oct 2020'	Erika Faust (b) (4) (b) (4)	09 Oct 2020 15:37:21

FDA-CBER-2022-1614-6051330

US3542168
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 26 Nov 2020 09:37:10
Was study treatment given?

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Oct 2020 04:17:01
User entered 'No (N)'	Erika Faust (b) (4) (b) (4)	09 Oct 2020 17:47:10

FDA-CBER-2022-1614-6051331

US3542168
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 26 Nov 2020 09:37:10
If No, reason not given

Audit	User	Time (GMT)
User closed query 'Per CDM: Please update the Study Discontinuation form accordingly if the subject was not given the study drug due to AE.' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 07:01:12
Query 'Per CDM: Please update the Study Discontinuation form accordingly if the subject was not given the study drug due to AE.' answered with 'Dosing discontinuation form updated' (Site from DM).	Hannah Yellin (b) (4) (b) (4)	19 Oct 2020 19:33:16
User opened query 'Per CDM: Please update the Study Discontinuation form accordingly if the subject was not given the study drug due to AE.' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 04:05:31
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Oct 2020 04:17:01
User entered 'Physician withheld dose due to Adverse Event (PHYSICIAN AE)'	Erika Faust (b) (4) (b) (4)	09 Oct 2020 17:47:10

FDA-CBER-2022-1614-6051332

US3542168
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 26 Nov 2020 09:37:10
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Oct 2020 04:17:01
User entered empty.	Erika Faust (b) (4) (b) (4)	09 Oct 2020 17:47:10

FDA-CBER-2022-1614-6051333

US3542168
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 26 Nov 2020 09:37:10
What was the study treatment?

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 17:47:10

FDA-CBER-2022-1614-6051334

US3542168
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 26 Nov 2020 09:37:10
What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Oct 2020 04:17:01
User entered empty.	Erika Faust (b) (4) (b) (4)	09 Oct 2020 17:47:10

FDA-CBER-2022-1614-6051335

US3542168
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 26 Nov 2020 09:37:10
What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Oct 2020 04:17:01
User entered empty.	Erika Faust (b) (4) (b) (4)	09 Oct 2020 17:47:10

FDA-CBER-2022-1614-6051336

US3542168
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 26 Nov 2020 09:37:10
Treatment Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 17:47:10

FDA-CBER-2022-1614-6051337

US3542168
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 26 Nov 2020 09:37:10
Which arm was used to give treatment?

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Oct 2020 04:17:01
User entered empty.	Erika Faust (b) (4) (b) (4)	09 Oct 2020 17:47:10

FDA-CBER-2022-1614-6051338

US3542168
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 26 Nov 2020 09:37:10
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 17:47:10

FDA-CBER-2022-1614-6051339

US3542168
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 26 Nov 2020 09:37:10
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 17:47:10

FDA-CBER-2022-1614-6051340

US3542168
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 26 Nov 2020 09:37:10
Was the sample collected?

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Oct 2020 04:17:01
User entered 'Yes (Y)'	Erika Faust (b) (4) (b) (4)	09 Oct 2020 17:48:34

FDA-CBER-2022-1614-6051341

US3542168
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 26 Nov 2020 09:37:10
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Oct 2020 04:17:01
User entered '8 Oct 2020'	Erika Faust (b) (4) (b) (4)	09 Oct 2020 17:48:34

FDA-CBER-2022-1614-6051342

US3542168
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 26 Nov 2020 09:37:10
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Oct 2020 04:17:01
User entered '11:40'	Erika Faust (b) (4) (b) (4)	09 Oct 2020 17:48:34

FDA-CBER-2022-1614-6051343

US3542168
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 26 Nov 2020 09:37:10
Collection date and time (derived)

Audit	User	Time (GMT)
User entered '8 Oct 2020 11:40'	System	09 Oct 2020 17:48:34

FDA-CBER-2022-1614-6051344

US3542168
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab
Generated On: 26 Nov 2020 09:37:10
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Oct 2020 04:17:01
User entered '8 Oct 2020'	Erika Faust (b) (4) (b) (4)	09 Oct 2020 17:49:02

FDA-CBER-2022-1614-6051345

US3542168
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 26 Nov 2020 09:37:10
Lab Test

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Erika Faust (b) (4) (b) (4)	09 Oct 2020 17:49:02

FDA-CBER-2022-1614-6051346

US3542168
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 26 Nov 2020 09:37:10
Was the sample collected?

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Oct 2020 04:17:01
User entered 'Yes (Y)'	Erika Faust (b) (4) (b) (4)	09 Oct 2020 17:49:02

FDA-CBER-2022-1614-6051347

US3542168
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 26 Nov 2020 09:37:10
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Oct 2020 04:17:01
User entered '11:15'	Erika Faust (b) (4) (b) (4)	09 Oct 2020 17:49:02

FDA-CBER-2022-1614-6051348

US3542168
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 26 Nov 2020 09:37:10
Collection date and time (derived)

Audit	User	Time (GMT)
User entered '8 Oct 2020 11:15'	System	09 Oct 2020 17:49:02

FDA-CBER-2022-1614-6051349

US3542168
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 26 Nov 2020 09:37:10
Lab Test

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Erika Faust (b) (4) (b) (4)	09 Oct 2020 17:49:02

FDA-CBER-2022-1614-6051350

US3542168
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 26 Nov 2020 09:37:10
Was the sample collected?

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Oct 2020 04:17:01
User entered 'No (N)'	Erika Faust (b) (4) (b) (4)	09 Oct 2020 17:49:02

FDA-CBER-2022-1614-6051351

US3542168
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 26 Nov 2020 09:37:10
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Oct 2020 04:17:01
User entered empty.	Erika Faust (b) (4) (b) (4)	09 Oct 2020 17:49:02

FDA-CBER-2022-1614-6051352

US3542168
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 26 Nov 2020 09:37:10
Collection date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 17:49:02

FDA-CBER-2022-1614-6051353

US3542168
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 26 Nov 2020 09:37:10
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	16 Oct 2020 04:17:01
User entered 'Yes (Y)'	Erika Faust (b) (4) (b) (4)	09 Oct 2020 17:49:11

FDA-CBER-2022-1614-6051354

US3542168
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 26 Nov 2020 09:37:10
Continuing Flag

Audit	User	Time (GMT)
User entered '1'	System	09 Oct 2020 17:49:11

FDA-CBER-2022-1614-6051355

US3542168
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 26 Nov 2020 09:37:10
Was Contact Attempted?

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Oct 2020 18:46:00
User entered 'Yes (Y)'	Erika Faust (b) (4) (b) (4)	16 Oct 2020 19:31:43

FDA-CBER-2022-1614-6051356

US3542168
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 26 Nov 2020 09:37:10
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Oct 2020 18:46:00
User entered '15 Oct 2020'	Erika Faust (b) (4) (b) (4)	16 Oct 2020 19:31:43

FDA-CBER-2022-1614-6051357

US3542168
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 26 Nov 2020 09:37:10
Please select one status for the follow-up contact

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Oct 2020 18:46:00
User entered 'Contact Made (CONTACT MADE)'	Erika Faust (b) (4) (b) (4)	16 Oct 2020 19:31:43

FDA-CBER-2022-1614-6051358

US3542168
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 26 Nov 2020 09:37:10
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Oct 2020 18:46:00
User entered empty.	Erika Faust (b) (4) (b) (4)	16 Oct 2020 19:31:43

FDA-CBER-2022-1614-6051359

US3542168
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 26 Nov 2020 09:37:10
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Oct 2020 18:46:00
User entered 'Yes (Y)'	Erika Faust (b) (4) (b) (4)	16 Oct 2020 19:31:47

FDA-CBER-2022-1614-6051360

US3542168
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 26 Nov 2020 09:37:10
Continuing Flag

Audit	User	Time (GMT)
User entered '1'	System	16 Oct 2020 19:31:47

FDA-CBER-2022-1614-6051361

US3542168
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 26 Nov 2020 09:37:10
Was Contact Attempted?

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	30 Oct 2020 01:28:16
User entered 'Yes (Y)'	DeEnna Wedding (b) (4) (b) (4)	23 Oct 2020 16:35:02

FDA-CBER-2022-1614-6051362

US3542168
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 26 Nov 2020 09:37:10
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	30 Oct 2020 01:28:16
User entered '22 Oct 2020'	DeEnna Wedding (b) (4) (b) (4)	23 Oct 2020 16:35:02

FDA-CBER-2022-1614-6051363

US3542168
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 26 Nov 2020 09:37:10
Please select one status for the follow-up contact

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	30 Oct 2020 01:28:16
User entered 'Contact Made (CONTACT MADE)'	DeEnna Wedding (b) (4) (b) (4)	23 Oct 2020 16:35:02

FDA-CBER-2022-1614-6051364

US3542168
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 26 Nov 2020 09:37:10
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	30 Oct 2020 01:28:16
User entered empty.	DeEnna Wedding (b) (4) (b) (4)	23 Oct 2020 16:35:02

FDA-CBER-2022-1614-6051365

US3542168
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 26 Nov 2020 09:37:10
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	30 Oct 2020 01:28:16
User entered 'Yes (Y)'	DeEnna Wedding (b) (4) (b) (4)	23 Oct 2020 16:35:07

FDA-CBER-2022-1614-6051366

US3542168
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 26 Nov 2020 09:37:10
Continuing Flag

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 16:35:07

FDA-CBER-2022-1614-6051367

US3542168
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 26 Nov 2020 09:37:10
Was Contact Attempted?

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	31 Oct 2020 18:33:49
User entered 'Yes (Y)'	Erika Faust (b) (4) (b) (4)	30 Oct 2020 16:18:37

FDA-CBER-2022-1614-6051368

US3542168
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 26 Nov 2020 09:37:10
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	31 Oct 2020 18:33:49
User entered '29 Oct 2020'	Erika Faust (b) (4) (b) (4)	30 Oct 2020 16:18:37

FDA-CBER-2022-1614-6051369

US3542168
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 26 Nov 2020 09:37:10
Please select one status for the follow-up contact

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	31 Oct 2020 18:33:49
User entered 'Contact Made (CONTACT MADE)'	Erika Faust (b) (4) (b) (4)	30 Oct 2020 16:18:37

FDA-CBER-2022-1614-6051370

US3542168
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 26 Nov 2020 09:37:10
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	31 Oct 2020 18:33:49
User entered empty.	Erika Faust (b) (4) (b) (4)	30 Oct 2020 16:18:37

FDA-CBER-2022-1614-6051371

US3542168
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 26 Nov 2020 09:37:10
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	31 Oct 2020 18:33:49
User entered 'Yes (Y)'	Erika Faust (b) (4) (b) (4)	30 Oct 2020 16:18:41

FDA-CBER-2022-1614-6051372

US3542168
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 26 Nov 2020 09:37:10
Continuing Flag

Audit	User	Time (GMT)
User entered '1'	System	30 Oct 2020 16:18:41

FDA-CBER-2022-1614-6051373

US3542168
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 26 Nov 2020 09:37:10
Was this visit performed?

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Nov 2020 04:15:40
User entered 'Yes (Y)'	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:22:55

FDA-CBER-2022-1614-6051374

US3542168
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 26 Nov 2020 09:37:10
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Nov 2020 04:15:40
User entered '12 Nov 2020'	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:22:55

FDA-CBER-2022-1614-6051375

US3542168
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 26 Nov 2020 09:37:10
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Nov 2020 04:15:40
User entered 'Clinic (Clinic)'	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:22:55

FDA-CBER-2022-1614-6051376

US3542168
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 26 Nov 2020 09:37:10
Folder OID

Audit	User	Time (GMT)
User entered 'VISIT3'	System	13 Nov 2020 17:22:55

FDA-CBER-2022-1614-6051377

US3542168
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 09:37:10
Were vital signs assessed?

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Nov 2020 04:15:40
User entered 'Yes (Y)'	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:28:53

FDA-CBER-2022-1614-6051378

US3542168
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 09:37:10
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Nov 2020 04:15:40
User entered '12 Nov 2020'	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:28:53

FDA-CBER-2022-1614-6051379

US3542168
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 09:37:10
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Nov 2020 04:15:40
User entered '12:56'	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:28:53

FDA-CBER-2022-1614-6051380

US3542168
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 09:37:10
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
User entered '12 Nov 2020 12:56'	System	13 Nov 2020 17:28:53

FDA-CBER-2022-1614-6051381

US3542168
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 09:37:10
Temperature *(xxx.x)*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Nov 2020 04:15:40
User entered '98.5' F	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:28:53

FDA-CBER-2022-1614-6051382

US3542168
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 09:37:10
Route of measurement

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Nov 2020 04:15:40
User entered 'Oral (Oral)'	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:28:53

FDA-CBER-2022-1614-6051383

US3542168
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 09:37:10
If Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Nov 2020 04:15:40
User entered empty.	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:28:53

FDA-CBER-2022-1614-6051384

US3542168
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 09:37:10
Pulse *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Nov 2020 04:15:40
User entered '58'	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:28:53

FDA-CBER-2022-1614-6051385

US3542168
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 09:37:10
Pulse units

Audit	User	Time (GMT)
User entered 'bpm'	System	13 Nov 2020 17:28:53

FDA-CBER-2022-1614-6051386

US3542168
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 09:37:10
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Nov 2020 04:15:40
User entered '17'	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:28:53

FDA-CBER-2022-1614-6051387

US3542168
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 09:37:10
Respiratory Rate units

Audit	User	Time (GMT)
User entered 'breaths/min'	System	13 Nov 2020 17:28:53

FDA-CBER-2022-1614-6051388

US3542168
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 09:37:10
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Nov 2020 04:15:40
User entered '138'	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:28:53

FDA-CBER-2022-1614-6051389

US3542168
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 09:37:10
Systolic Blood Pressure units

Audit	User	Time (GMT)
User entered 'mmHg'	System	13 Nov 2020 17:28:53

FDA-CBER-2022-1614-6051390

US3542168
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 09:37:10
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Nov 2020 04:15:40
User entered '76'	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:28:53

FDA-CBER-2022-1614-6051391

US3542168
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 26 Nov 2020 09:37:10
Diastolic Blood Pressure units

Audit	User	Time (GMT)
User entered 'mmHg'	System	13 Nov 2020 17:28:53

FDA-CBER-2022-1614-6051392

US3542168
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Generated On: 26 Nov 2020 09:37:10
Was the physical examination performed?

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Nov 2020 04:15:40
User entered 'Yes (Y)'	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:22:46

FDA-CBER-2022-1614-6051393

US3542168
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Generated On: 26 Nov 2020 09:37:10
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Nov 2020 04:15:40
User entered '12 Nov 2020'	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:22:46

FDA-CBER-2022-1614-6051394

US3542168
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 26 Nov 2020 09:37:10
Was the sample collected?

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Nov 2020 04:15:40
User entered 'Yes (Y)'	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:22:33

FDA-CBER-2022-1614-6051395

US3542168
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 26 Nov 2020 09:37:10
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Nov 2020 04:15:40
User entered '12 Nov 2020'	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:22:33

FDA-CBER-2022-1614-6051396

US3542168
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 26 Nov 2020 09:37:10
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Nov 2020 04:15:40
User entered '12:57'	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:22:33

FDA-CBER-2022-1614-6051397

US3542168
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 26 Nov 2020 09:37:10
Collection date and time (derived)

Audit	User	Time (GMT)
User entered '12 Nov 2020 12:57'	System	13 Nov 2020 17:22:33

FDA-CBER-2022-1614-6051398

US3542168
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 26 Nov 2020 09:37:10
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Nov 2020 04:15:40
User entered 'Yes (Y)'	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:22:13

FDA-CBER-2022-1614-6051399

US3542168
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 26 Nov 2020 09:37:10
Continuing Flag

Audit	User	Time (GMT)
User entered '1'	System	13 Nov 2020 17:22:13

FDA-CBER-2022-1614-6051400

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 64'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051401

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '04 Nov 2020 00:01'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051402

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '08 Nov 2020 23:59'	System	04 Sep 2020 20:20:50

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 71'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051404

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '11 Nov 2020 00:01'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051405

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '15 Nov 2020 23:59'	System	04 Sep 2020 20:20:50

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 78'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051407

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '18 Nov 2020 00:01'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051408

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '22 Nov 2020 23:59'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051409

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 92'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051410

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '02 Dec 2020 00:01'	System	04 Sep 2020 20:20:50

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '06 Dec 2020 23:59'	System	04 Sep 2020 20:20:50

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 99'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051413

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '09 Dec 2020 00:01'	System	04 Sep 2020 20:20:50

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '13 Dec 2020 23:59'	System	04 Sep 2020 20:20:50

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 106'	System	04 Sep 2020 20:20:50

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '16 Dec 2020 00:01'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051417

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '20 Dec 2020 23:59'	System	04 Sep 2020 20:20:50

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 113'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051419

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '23 Dec 2020 00:01'	System	04 Sep 2020 20:20:50

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '27 Dec 2020 23:59'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051421

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 126'	System	04 Sep 2020 20:20:50

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '05 Jan 2021 00:01'	System	04 Sep 2020 20:20:50

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '09 Jan 2021 23:59'	System	04 Sep 2020 20:20:50

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 133'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051425

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '12 Jan 2021 00:01'	System	04 Sep 2020 20:20:50

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '16 Jan 2021 23:59'	System	04 Sep 2020 20:20:50

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 140'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051428

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '19 Jan 2021 00:01'	System	04 Sep 2020 20:20:50

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '23 Jan 2021 23:59'	System	04 Sep 2020 20:20:50

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 154'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051431

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '02 Feb 2021 00:01'	System	04 Sep 2020 20:20:50

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '06 Feb 2021 23:59'	System	04 Sep 2020 20:20:50

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 161'	System	04 Sep 2020 20:20:50

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '09 Feb 2021 00:01'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051435

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '13 Feb 2021 23:59'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051436

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 168'	System	04 Sep 2020 20:20:50

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '16 Feb 2021 00:01'	System	04 Sep 2020 20:20:50

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '20 Feb 2021 23:59'	System	04 Sep 2020 20:20:50

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 182'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051440

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '02 Mar 2021 00:01'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051441

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '06 Mar 2021 23:59'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051442

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 189'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051443

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '09 Mar 2021 00:01'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051444

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '13 Mar 2021 23:59'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051445

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 196'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051446

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '16 Mar 2021 00:01'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051447

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '20 Mar 2021 23:59'	System	04 Sep 2020 20:20:50

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 203'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051449

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '23 Mar 2021 00:01'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051450

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '27 Mar 2021 23:59'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051451

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 216'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051452

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '05 Apr 2021 00:01'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051453

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '09 Apr 2021 23:59'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051454

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 223'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051455

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '12 Apr 2021 00:01'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051456

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '16 Apr 2021 23:59'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051457

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 230'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051458

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '19 Apr 2021 00:01'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051459

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '23 Apr 2021 23:59'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051460

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 246'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051461

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '05 May 2021 00:01'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051462

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '09 May 2021 23:59'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051463

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 253'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051464

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '12 May 2021 00:01'	System	04 Sep 2020 20:20:50

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '16 May 2021 23:59'	System	04 Sep 2020 20:20:50

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 260'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051467

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '19 May 2021 00:01'	System	04 Sep 2020 20:20:50

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '23 May 2021 23:59'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051469

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 276'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051470

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '04 Jun 2021 00:01'	System	04 Sep 2020 20:20:50

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '08 Jun 2021 23:59'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051472

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 283'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051473

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '11 Jun 2021 00:01'	System	04 Sep 2020 20:20:50

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '15 Jun 2021 23:59'	System	04 Sep 2020 20:20:50

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 290'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051476

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '18 Jun 2021 00:01'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051477

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '22 Jun 2021 23:59'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051478

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 306'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051479

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '04 Jul 2021 00:01'	System	04 Sep 2020 20:20:50

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '08 Jul 2021 23:59'	System	04 Sep 2020 20:20:50

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 313'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051482

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '11 Jul 2021 00:01'	System	04 Sep 2020 20:20:50

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '15 Jul 2021 23:59'	System	04 Sep 2020 20:20:50

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 320'	System	04 Sep 2020 20:20:50

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '18 Jul 2021 00:01'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051486

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '22 Jul 2021 23:59'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051487

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 336'	System	04 Sep 2020 20:20:50

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '03 Aug 2021 00:01'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051489

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '07 Aug 2021 23:59'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051490

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 343'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051491

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '10 Aug 2021 00:01'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051492

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '14 Aug 2021 23:59'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051493

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 350'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051494

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '17 Aug 2021 00:01'	System	04 Sep 2020 20:20:50

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '21 Aug 2021 23:59'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051496

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 366'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051497

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '02 Sep 2021 00:01'	System	04 Sep 2020 20:20:50

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '06 Sep 2021 23:59'	System	04 Sep 2020 20:20:50

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 373'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051500

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '09 Sep 2021 00:01'	System	04 Sep 2020 20:20:50

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '13 Sep 2021 23:59'	System	04 Sep 2020 20:20:50

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 380'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051503

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '16 Sep 2021 00:01'	System	04 Sep 2020 20:20:50

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '20 Sep 2021 23:59'	System	04 Sep 2020 20:20:50

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 387'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051506

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '23 Sep 2021 00:01'	System	04 Sep 2020 20:20:50

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '27 Sep 2021 23:59'	System	04 Sep 2020 20:20:50

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 401'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051509

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '07 Oct 2021 00:01'	System	04 Sep 2020 20:20:50

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '11 Oct 2021 23:59'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051511

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 408'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051512

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '14 Oct 2021 00:01'	System	04 Sep 2020 20:20:50

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '18 Oct 2021 23:59'	System	04 Sep 2020 20:20:50

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 415'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051515

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '21 Oct 2021 00:01'	System	04 Sep 2020 20:20:50

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '25 Oct 2021 23:59'	System	04 Sep 2020 20:20:50

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 431'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051518

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '06 Nov 2021 00:01'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051519

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '10 Nov 2021 23:59'	System	04 Sep 2020 20:20:50

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 438'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051521

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '13 Nov 2021 00:01'	System	04 Sep 2020 20:20:50

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '17 Nov 2021 23:59'	System	04 Sep 2020 20:20:50

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 445'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051524

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '20 Nov 2021 00:01'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051525

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '24 Nov 2021 23:59'	System	04 Sep 2020 20:20:50

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 461'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051527

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '06 Dec 2021 00:01'	System	04 Sep 2020 20:20:50

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '10 Dec 2021 23:59'	System	04 Sep 2020 20:20:50

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 468'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051530

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '13 Dec 2021 00:01'	System	04 Sep 2020 20:20:50

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '17 Dec 2021 23:59'	System	04 Sep 2020 20:20:50

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 475'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051533

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '20 Dec 2021 00:01'	System	04 Sep 2020 20:20:50

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '24 Dec 2021 23:59'	System	04 Sep 2020 20:20:50

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 491'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051536

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '05 Jan 2022 00:01'	System	04 Sep 2020 20:20:50

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '09 Jan 2022 23:59'	System	04 Sep 2020 20:20:50

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 498'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051539

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '12 Jan 2022 00:01'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051540

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '16 Jan 2022 23:59'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051541

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 505'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051542

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '19 Jan 2022 00:01'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051543

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '23 Jan 2022 23:59'	System	04 Sep 2020 20:20:50

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 521'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051545

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '04 Feb 2022 00:01'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051546

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '08 Feb 2022 23:59'	System	04 Sep 2020 20:20:50

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 528'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051548

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '11 Feb 2022 00:01'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051549

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '15 Feb 2022 23:59'	System	04 Sep 2020 20:20:50

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 535'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051551

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '18 Feb 2022 00:01'	System	04 Sep 2020 20:20:50

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '22 Feb 2022 23:59'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051553

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 551'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051554

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '06 Mar 2022 00:01'	System	04 Sep 2020 20:20:50

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '10 Mar 2022 23:59'	System	04 Sep 2020 20:20:50

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 558'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051557

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '13 Mar 2022 00:01'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051558

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '17 Mar 2022 23:59'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051559

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 565'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051560

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '20 Mar 2022 00:01'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051561

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '24 Mar 2022 23:59'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051562

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 572'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051563

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '27 Mar 2022 00:01'	System	04 Sep 2020 20:20:50

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '31 Mar 2022 23:59'	System	04 Sep 2020 20:20:50

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 579'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051566

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '03 Apr 2022 00:01'	System	04 Sep 2020 20:20:50

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '07 Apr 2022 23:59'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051568

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 586'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051569

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '10 Apr 2022 00:01'	System	04 Sep 2020 20:20:50

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '14 Apr 2022 23:59'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051571

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 595'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051572

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '19 Apr 2022 00:01'	System	04 Sep 2020 20:20:50

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '23 Apr 2022 23:59'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051574

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 611'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051575

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '05 May 2022 00:01'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051576

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '09 May 2022 23:59'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051577

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 618'	System	04 Sep 2020 20:20:50

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '12 May 2022 00:01'	System	04 Sep 2020 20:20:50

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '16 May 2022 23:59'	System	04 Sep 2020 20:20:50

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 625'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051581

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '19 May 2022 00:01'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051582

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '23 May 2022 23:59'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051583

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 641'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051584

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '04 Jun 2022 00:01'	System	04 Sep 2020 20:20:50

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '08 Jun 2022 23:59'	System	04 Sep 2020 20:20:50

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 648'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051587

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '11 Jun 2022 00:01'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051588

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '15 Jun 2022 23:59'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051589

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 655'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051590

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '18 Jun 2022 00:01'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051591

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '22 Jun 2022 23:59'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051592

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 671'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051593

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '04 Jul 2022 00:01'	System	04 Sep 2020 20:20:50

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '08 Jul 2022 23:59'	System	04 Sep 2020 20:20:50

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 678'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051596

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '11 Jul 2022 00:01'	System	04 Sep 2020 20:20:50

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '15 Jul 2022 23:59'	System	04 Sep 2020 20:20:50

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 685'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051599

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '18 Jul 2022 00:01'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051600

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '22 Jul 2022 23:59'	System	04 Sep 2020 20:20:50

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 701'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051602

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '03 Aug 2022 00:01'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051603

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '07 Aug 2022 23:59'	System	04 Sep 2020 20:20:50

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 708'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051605

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '10 Aug 2022 00:01'	System	04 Sep 2020 20:20:50

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '14 Aug 2022 23:59'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051607

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 715'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051608

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '17 Aug 2022 00:01'	System	04 Sep 2020 20:20:50

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '21 Aug 2022 23:59'	System	04 Sep 2020 20:20:50

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 731'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051611

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '02 Sep 2022 00:01'	System	04 Sep 2020 20:20:50

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '06 Sep 2022 23:59'	System	04 Sep 2020 20:20:50

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 738'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051614

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '09 Sep 2022 00:01'	System	04 Sep 2020 20:20:50

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '13 Sep 2022 23:59'	System	04 Sep 2020 20:20:50

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 745'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051617

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '16 Sep 2022 00:01'	System	04 Sep 2020 20:20:50

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '20 Sep 2022 23:59'	System	04 Sep 2020 20:20:50

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered 'Day 752'	System	04 Sep 2020 20:20:50

FDA-CBER-2022-1614-6051620

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '23 Sep 2022 00:01'	System	04 Sep 2020 20:20:50

US3542168
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 26 Nov 2020 09:37:10
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 20:20:50
User entered '27 Sep 2022 23:59'	System	04 Sep 2020 20:20:50

US3542168
Folder: Adverse Events
Form: Adverse Events Summary
Generated On: 26 Nov 2020 09:37:10
Did the participant experience any adverse events?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:19:16
User signature succeeded.	David Diemert (b) (4) (b) (4)	18 Sep 2020 17:11:07
User entered 'Yes (Y)'	David Diemert (b) (4) (b) (4)	18 Sep 2020 17:10:59

FDA-CBER-2022-1614-6051623

US3542168
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:37:10
AEID

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:52:51
User entered 'USA-US084-2020-mRNA-1273-P301000001'	System	20 Sep 2020 17:52:47
User entered 'New'	(b) (4), (b) (6)	20 Sep 2020 17:52:47

FDA-CBER-2022-1614-6051624

US3542168
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:37:10
Adverse event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:57:34
User closed query 'PV Query: Please consider keeping one event of anxiety exacerbation instead of two episodes, capture hospitalization dates from 10Sep to 23Sep, and event start date 10Sep and event end date 23Sep.' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 16:14:03
Query 'PV Query: Please consider keeping one event of anxiety exacerbation instead of two episodes, capture hospitalization dates from 10Sep to 23Sep, and event start date 10Sep and event end date 23Sep.' answered with 'These are considered two discrete events from a clinical perspective' (Site from Safety).	Elissa Malkin (b) (4) (b) (4)	09 Nov 2020 21:06:57
User opened query 'PV Query: Please consider keeping one event of anxiety exacerbation instead of two episodes, capture hospitalization dates from 10Sep to 23Sep, and event start date 10Sep and event end date 23Sep.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 01:50:46
User signature succeeded.	David Diemert (b) (4) (b) (4)	31 Oct 2020 18:33:49
User closed query 'Per DM CLR: Please confirm if this AE is a worsening of the same condition noted in the MH eCRF. If yes, please update the AE term to reflect the term 'worsening or exacerbation' and ensure any Con Med indications are updated if required. Otherwise, If this is a duplicate please confirm if it meets the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 08:43:46
User closed query 'PV Query: Please consider updating the event term to "worsening of anxiety" if it matches the investigator's diagnosis and consider keeping one event instead of two episodes with capturing hospitalization dates from 10Sep to 23Sep.' (Site from Safety).	(b) (4), (b) (6)	28 Oct 2020 18:05:48
Query 'Per DM CLR: Please confirm if this AE is a worsening of the same condition noted in the MH eCRF. If yes, please update the AE term to reflect the term 'worsening or exacerbation' and ensure any Con Med indications are updated if required. Otherwise, If this is a duplicate please confirm if it meets the AE reporting criteria. ' answered with 'Updated.' (Site from DM).	David Diemert (b) (4) (b) (4)	27 Oct 2020 20:20:11

FDA-CBER-2022-1614-6051625

US3542168
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:37:10
Adverse event

Audit	User	Time (GMT)
Query 'PV Query: Please consider updating the event term to "worsening of anxiety" if it matches the investigator's diagnosis and consider keeping one event instead of two episodes with capturing hospitalization dates from 10Sep to 23Sep.' answered with 'Clarified.' (Site from Safety).	David Diemert (b) (4) (b) (4)	27 Oct 2020 20:20:01
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Exacerbation of anxiety - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Oct 2020 20:19:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Oct 2020 20:19:28
Data point term sent to Coder	System	27 Oct 2020 20:18:45
DataPoint Un-verified.	David Diemert (b) (4) (b) (4)	27 Oct 2020 20:18:43
Coding entries removed.	David Diemert (b) (4) (b) (4)	27 Oct 2020 20:18:43
Signature has been broken.	David Diemert (b) (4) (b) (4)	27 Oct 2020 20:18:43
User entered 'ANXIETY Exacerbation' reason for change: Per Query Resolution	David Diemert (b) (4) (b) (4)	27 Oct 2020 20:18:43
User opened query 'Per DM CLR: Please confirm if this AE is a worsening of the same condition noted in the MH eCRF. If yes, please update the AE term to reflect the term 'worsening or exacerbation' and ensure any Con Med indications are updated if required. Otherwise, If this is a duplicate please confirm if it meets the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 09:29:17
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User opened query 'PV Query: Please consider updating the event term to "worsening of anxiety" if it matches the investigator's diagnosis and consider keeping one event instead of two episodes with capturing hospitalization dates from 10Sep to 23Sep.' (Site from Safety).	(b) (4), (b) (6)	06 Oct 2020 12:07:25
Query 'PV Query: Please consider updating the event term to "worsening of anxiety" if it matches the investigator's diagnosis.' canceled (Site from Safety).	(b) (4), (b) (6)	28 Sep 2020 22:03:59

FDA-CBER-2022-1614-6051626

US3542168
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:37:10
Adverse event

Audit	User	Time (GMT)
User opened query 'PV Query: Please consider updating the event term to "worsening of anxiety" if it matches the investigator's diagnosis.' (Site from Safety).	(b) (4), (b) (6)	28 Sep 2020 18:39:41
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Sep 2020 17:46:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Sep 2020 17:46:41
Data point term sent to Coder	System	18 Sep 2020 17:45:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	18 Sep 2020 17:45:19
User entered 'Anxiety'	David Diemert (b) (4) (b) (4)	18 Sep 2020 17:45:07

FDA-CBER-2022-1614-6051627

US3542168
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:37:10
Was this a medically-attended AE?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	18 Sep 2020 17:45:19
User entered 'Yes (Y)'	David Diemert (b) (4) (b) (4)	18 Sep 2020 17:45:07

FDA-CBER-2022-1614-6051628

US3542168
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:37:10
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	18 Sep 2020 17:45:19
User entered 'No (N)'	David Diemert (b) (4) (b) (4)	18 Sep 2020 17:45:07

FDA-CBER-2022-1614-6051629

US3542168
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:37:10
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	18 Sep 2020 17:45:19
User entered 'No (N)'	David Diemert (b) (4) (b) (4)	18 Sep 2020 17:45:07

FDA-CBER-2022-1614-6051630

US3542168
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:37:10
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	18 Sep 2020 17:45:19
User entered '10 Sep 2020'	David Diemert (b) (4) (b) (4)	18 Sep 2020 17:45:07

FDA-CBER-2022-1614-6051631

US3542168
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:37:10
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	18 Sep 2020 17:45:19
User entered empty.	David Diemert (b) (4) (b) (4)	18 Sep 2020 17:45:07

FDA-CBER-2022-1614-6051632

US3542168
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:37:10
AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 17:45:07

FDA-CBER-2022-1614-6051633

US3542168
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:37:10
Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	18 Sep 2020 17:45:19
User entered 'No (N)'	David Diemert (b) (4) (b) (4)	18 Sep 2020 17:45:07

FDA-CBER-2022-1614-6051634

US3542168
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:37:10
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	18 Sep 2020 17:45:19
User entered '18 Sep 2020'	David Diemert (b) (4) (b) (4)	18 Sep 2020 17:45:07

FDA-CBER-2022-1614-6051635

US3542168
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:37:10
End time *(00:00-23:59)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	18 Sep 2020 17:45:19
User entered empty.	David Diemert (b) (4) (b) (4)	18 Sep 2020 17:45:07

FDA-CBER-2022-1614-6051636

US3542168
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:37:10
AE End Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 17:45:07

FDA-CBER-2022-1614-6051637

US3542168
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:37:10
Severity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	18 Sep 2020 17:45:19
User entered 'Grade 4 (Grade 4)'	David Diemert (b) (4) (b) (4)	18 Sep 2020 17:45:07

FDA-CBER-2022-1614-6051638

US3542168
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:37:10
Is the adverse event serious?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	18 Sep 2020 17:45:19
User entered 'Yes (Y)'	David Diemert (b) (4) (b) (4)	18 Sep 2020 17:45:07

FDA-CBER-2022-1614-6051639

US3542168
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:37:10
Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	18 Sep 2020 17:45:19
User entered '0'	David Diemert (b) (4) (b) (4)	18 Sep 2020 17:45:07

FDA-CBER-2022-1614-6051640

US3542168
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:37:10
Life threatening

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	18 Sep 2020 17:45:19
User entered '0'	David Diemert (b) (4) (b) (4)	18 Sep 2020 17:45:07

FDA-CBER-2022-1614-6051641

US3542168
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:37:10
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	18 Sep 2020 17:45:19
User entered '1'	David Diemert (b) (4) (b) (4)	18 Sep 2020 17:45:07

FDA-CBER-2022-1614-6051642

US3542168
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:37:10
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	18 Sep 2020 17:45:19
User entered '10 Sep 2020'	David Diemert (b) (4) (b) (4)	18 Sep 2020 17:45:07

FDA-CBER-2022-1614-6051643

US3542168
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:37:10
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	18 Sep 2020 17:45:19
User entered '18 Sep 2020'	David Diemert (b) (4) (b) (4)	18 Sep 2020 17:45:07

FDA-CBER-2022-1614-6051644

US3542168
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:37:10
Admitted to ICU?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	18 Sep 2020 17:45:19
User entered 'No (N)'	David Diemert (b) (4) (b) (4)	18 Sep 2020 17:45:07

FDA-CBER-2022-1614-6051645

US3542168
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:37:10
Number of Days in ICU

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	18 Sep 2020 17:45:19
User entered empty.	David Diemert (b) (4) (b) (4)	18 Sep 2020 17:45:07

FDA-CBER-2022-1614-6051646

US3542168
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:37:10
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	18 Sep 2020 17:45:19
User entered '0'	David Diemert (b) (4) (b) (4)	18 Sep 2020 17:45:07

FDA-CBER-2022-1614-6051647

US3542168
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:37:10
Congenital anomaly or birth defect

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	18 Sep 2020 17:45:19
User entered '0'	David Diemert (b) (4) (b) (4)	18 Sep 2020 17:45:07

FDA-CBER-2022-1614-6051648

US3542168
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:37:10
Other medically important event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	18 Sep 2020 17:45:19
User entered '0'	David Diemert (b) (4) (b) (4)	18 Sep 2020 17:45:07

FDA-CBER-2022-1614-6051649

US3542168
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:37:10
Relationship to investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	18 Sep 2020 17:45:19
User entered 'Not Related (NOT RELATED)'	David Diemert (b) (4) (b) (4)	18 Sep 2020 17:45:07

FDA-CBER-2022-1614-6051650

US3542168
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:37:10
Relationship to Study Procedure

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	18 Sep 2020 17:45:19
User entered 'Not Related (NOT RELATED)'	David Diemert (b) (4) (b) (4)	18 Sep 2020 17:45:07

FDA-CBER-2022-1614-6051651

US3542168
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:37:10
Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	18 Sep 2020 17:45:19
User entered 'None (NONE)'	David Diemert (b) (4) (b) (4)	18 Sep 2020 17:45:07

FDA-CBER-2022-1614-6051652

US3542168
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:37:10
None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	18 Sep 2020 17:45:19
User entered '0'	David Diemert (b) (4) (b) (4)	18 Sep 2020 17:45:07

FDA-CBER-2022-1614-6051653

US3542168
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:37:10
Concomitant Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	18 Sep 2020 17:45:19
User entered '1'	David Diemert (b) (4) (b) (4)	18 Sep 2020 17:45:07

FDA-CBER-2022-1614-6051654

US3542168
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:37:10
Concomitant Procedure

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	18 Sep 2020 17:45:19
User entered '0'	David Diemert (b) (4) (b) (4)	18 Sep 2020 17:45:07

FDA-CBER-2022-1614-6051655

US3542168
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:37:10
Outcome

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	18 Sep 2020 17:45:19
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	David Diemert (b) (4) (b) (4)	18 Sep 2020 17:45:07

FDA-CBER-2022-1614-6051656

US3542168
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:37:10
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	18 Sep 2020 17:45:19
User entered empty.	David Diemert (b) (4) (b) (4)	18 Sep 2020 17:45:07

FDA-CBER-2022-1614-6051657

US3542168
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:37:10
Narrative

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. Please leave query open until information is received.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 01:51:42
User closed query 'PV Query: Please provide the start date for the concomitant medication, hydroxyurea.' (Site from Safety).	(b) (4), (b) (6)	28 Oct 2020 18:05:56
Query 'PV Query: Please provide the start date for the concomitant medication, hydroxyurea.' answered with 'This was corrected on the Con Med log.' (Site from Safety).	David Diemert (b) (4) (b) (4)	27 Oct 2020 20:22:20
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User opened query 'PV Query: Please provide the start date for the concomitant medication, hydroxyurea.' (Site from Safety).	(b) (4), (b) (6)	06 Oct 2020 12:08:31
Query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). As mentioned, please add Remeron as a concomitant medication.' canceled (Site from Safety).	(b) (4), (b) (6)	28 Sep 2020 22:04:52
Query 'PV Query: Please add subject's medical history (prior to onset of study) to medical history eCRF. As mentioned, anxiety and depression should be captured as medical histories.' canceled (Site from Safety).	(b) (4), (b) (6)	28 Sep 2020 22:04:49
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' canceled (Site from Safety).	(b) (4), (b) (6)	28 Sep 2020 22:04:44
User opened query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). As mentioned, please add Remeron as a concomitant medication.' (Site from Safety).	(b) (4), (b) (6)	28 Sep 2020 18:39:15

FDA-CBER-2022-1614-6051658

US3542168
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:37:10
Narrative

Audit	User	Time (GMT)
User opened query 'PV Query: Please add subject's medical history (prior to onset of study) to medical history eCRF. As mentioned, anxiety and depression should be captured as medical histories.' (Site from Safety).	(b) (4), (b) (6)	28 Sep 2020 18:39:02
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	28 Sep 2020 18:38:50
User signature succeeded.	David Diemert (b) (4) (b) (4)	18 Sep 2020 17:45:19
User entered 'Participant reported to site on 18SEP2020 that he had just been discharged from hospital this day after having been admitted to the psychiatric service on 10SEP2020 due to worsened anxiety. He states that he has pre-existing diagnoses of anxiety and depression for the past 20 years that were not related to the study team at screening/enrollment. He has been treated for the past year with Remeron 15mg/day (also not reported to the study team at screening/enrollment). According to the participant, his girlfriend was recently diagnosed with cervical cancer, which led to worsened symptoms of anxiety on 10SEP2020, prompting him to go to the Emergency Department of a local community hospital (not at the study site). He was admitted to the Psychiatry service for medication adjustment. His dose of Remeron was increased to 30mg/day according to the participant. During his in-patient stay his symptoms of anxiety improved and he was therefore discharged home the morning of 18SEP2020. He will follow-up with his regular psychiatrist. He denies having any potential COVID-19 symptoms: no fever, chills, dyspnea, cough, loss of taste or smell, rhinorrhea, nasal congestion, sore throat, myalgias, arthralgias, headache, fatigue, nausea, or diarrhea. No recent travel or sick contacts. He received his first dose of vaccine/placebo on 04SEPT2020.'	David Diemert (b) (4) (b) (4)	18 Sep 2020 17:45:07

FDA-CBER-2022-1614-6051659

US3542168
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:37:10
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 17:45:07

FDA-CBER-2022-1614-6051660

US3542168
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:37:10
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 17:45:07

FDA-CBER-2022-1614-6051661

US3542168
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 26 Nov 2020 09:37:10
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	18 Sep 2020 17:45:07

FDA-CBER-2022-1614-6051662

US3542168
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 26 Nov 2020 09:37:10
AEID

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:31:49
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:00:42
User entered 'USA-US084-2020-mRNA-1273-P301000001'	(b) (4), (b) (6)	28 Sep 2020 14:00:30

FDA-CBER-2022-1614-6051663

US3542168
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 26 Nov 2020 09:37:10
Adverse event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:57:27
User signature succeeded.	David Diemert (b) (4)	31 Oct 2020 18:33:49
User closed query 'Per DM CLR: Review if this AE is related to the previously recorded AE #2 (10 SEP 2020). Note that downgrades in intensity are not recorded as separate AEs. The highest grade of the AE remains ongoing until event resolves. Review and update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 08:43:58
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Exacerbation of anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	27 Oct 2020 20:25:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	27 Oct 2020 20:25:40
Data point term sent to Coder	System	27 Oct 2020 20:24:55
Query 'Per DM CLR: Review if this AE is related to the previously recorded AE #2 (10 SEP 2020). Note that downgrades in intensity are not recorded as separate AEs. The highest grade of the AE remains ongoing until event resolves. Review and update eCRF as appropriate. ' answered with 'This individual had two separate episodes of anxiety exacerbation, with resolution in between them.' (Site from DM).	David Diemert (b) (4)	27 Oct 2020 20:24:02
DataPoint Un-verified.	David Diemert (b) (4)	27 Oct 2020 20:23:56
Coding entries removed.	David Diemert (b) (4)	27 Oct 2020 20:23:56
Signature has been broken.	David Diemert (b) (4)	27 Oct 2020 20:23:56
User entered 'ANXIETY Exacerbation' reason for change: New Information	David Diemert (b) (4)	27 Oct 2020 20:23:56
User opened query 'Per DM CLR: Review if this AE is related to the previously recorded AE #2 (10 SEP 2020). Note that downgrades in intensity are not recorded as separate AEs. The highest grade of the AE remains ongoing until event resolves. Review and update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 09:29:40

FDA-CBER-2022-1614-6051664

US3542168
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 26 Nov 2020 09:37:10
Adverse event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety disorders NEC, PT: Anxiety disorder, LLT: Anxiety disorder - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Sep 2020 22:26:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Sep 2020 22:26:53
User signature succeeded.	David Diemert (b) (4) (b) (4)	26 Sep 2020 22:26:17
Data point term sent to Coder	System	26 Sep 2020 22:26:08
User entered 'Anxiety Disorder'	David Diemert (b) (4) (b) (4)	26 Sep 2020 22:25:44

FDA-CBER-2022-1614-6051665

US3542168
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 26 Nov 2020 09:37:10
Was this a medically-attended AE?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	26 Sep 2020 22:26:17
User entered 'Yes (Y)'	David Diemert (b) (4) (b) (4)	26 Sep 2020 22:25:44

FDA-CBER-2022-1614-6051666

US3542168
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 26 Nov 2020 09:37:10
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	26 Sep 2020 22:26:17
User entered 'No (N)'	David Diemert (b) (4) (b) (4)	26 Sep 2020 22:25:44

FDA-CBER-2022-1614-6051667

US3542168
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 26 Nov 2020 09:37:10
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User closed query 'PV Query Urgent: Is this an event of positive Covid-19? If yes, please update event term to Covid-19 and add results under Covid Diagnostic Test in the Covid-19 Assessments tab. If no, please change answer to No.' (Site from Safety).	(b) (4), (b) (6)	30 Sep 2020 12:37:20
Query 'PV Query Urgent: Is this an event of positive Covid-19? If yes, please update event term to Covid-19 and add results under Covid Diagnostic Test in the Covid-19 Assessments tab. If no, please change answer to No.' answered with 'Field updated to no' (Site from Safety).	Hannah Yellin (b) (4) (b) (4)	29 Sep 2020 20:59:48
Signature has been broken.	Hannah Yellin (b) (4) (b) (4)	29 Sep 2020 20:59:31
User entered 'No (N)' reason for change: Data Entry Error	Hannah Yellin (b) (4) (b) (4)	29 Sep 2020 20:59:31
User opened query 'PV Query Urgent: Is this an event of positive Covid-19? If yes, please update event term to Covid-19 and add results under Covid Diagnostic Test in the Covid-19 Assessments tab. If no, please change answer to No.' (Site from Safety).	(b) (4), (b) (6)	29 Sep 2020 13:51:38
User signature succeeded.	David Diemert (b) (4) (b) (4)	26 Sep 2020 22:26:17
User entered 'Yes (Y)'	David Diemert (b) (4) (b) (4)	26 Sep 2020 22:25:44

FDA-CBER-2022-1614-6051668

US3542168
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 26 Nov 2020 09:37:10
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	26 Sep 2020 22:26:17
User entered '19 Sep 2020'	David Diemert (b) (4) (b) (4)	26 Sep 2020 22:25:44

FDA-CBER-2022-1614-6051669

US3542168
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 26 Nov 2020 09:37:10
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	26 Sep 2020 22:26:17
User entered empty.	David Diemert (b) (4) (b) (4)	26 Sep 2020 22:25:44

FDA-CBER-2022-1614-6051670

US3542168
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 26 Nov 2020 09:37:10
AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	26 Sep 2020 22:25:44

FDA-CBER-2022-1614-6051671

US3542168
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 26 Nov 2020 09:37:10
Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	26 Sep 2020 22:26:17
User entered 'No (N)'	David Diemert (b) (4) (b) (4)	26 Sep 2020 22:25:44

FDA-CBER-2022-1614-6051672

US3542168
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 26 Nov 2020 09:37:10
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	26 Sep 2020 22:26:17
User entered '23 Sep 2020'	David Diemert (b) (4) (b) (4)	26 Sep 2020 22:25:44

FDA-CBER-2022-1614-6051673

US3542168
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 26 Nov 2020 09:37:10
End time *(00:00-23:59)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	26 Sep 2020 22:26:17
User entered empty.	David Diemert (b) (4) (b) (4)	26 Sep 2020 22:25:44

FDA-CBER-2022-1614-6051674

US3542168
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 26 Nov 2020 09:37:10
AE End Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	26 Sep 2020 22:25:44

FDA-CBER-2022-1614-6051675

US3542168
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 26 Nov 2020 09:37:10
Severity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	26 Sep 2020 22:26:17
User entered 'Grade 3/Severe (Grade 3/Severe)'	David Diemert (b) (4) (b) (4)	26 Sep 2020 22:25:44

US3542168
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 26 Nov 2020 09:37:10
Is the adverse event serious?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	26 Sep 2020 22:26:17
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	26 Sep 2020 22:26:06
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	26 Sep 2020 22:25:44
User entered 'Yes (Y)'	David Diemert (b) (4) (b) (4)	26 Sep 2020 22:25:44

FDA-CBER-2022-1614-6051677

US3542168
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 26 Nov 2020 09:37:10
Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	26 Sep 2020 22:26:17
User entered '0'	David Diemert (b) (4) (b) (4)	26 Sep 2020 22:25:44

FDA-CBER-2022-1614-6051678

US3542168
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 26 Nov 2020 09:37:10
Life threatening

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	26 Sep 2020 22:26:17
User entered '0'	David Diemert (b) (4) (b) (4)	26 Sep 2020 22:25:44

FDA-CBER-2022-1614-6051679

US3542168
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 26 Nov 2020 09:37:10
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	26 Sep 2020 22:26:17
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	26 Sep 2020 22:26:06
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).	System	26 Sep 2020 22:26:06
User entered '1' reason for change: Data Entry Error	David Diemert (b) (4) (b) (4)	26 Sep 2020 22:26:06
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	26 Sep 2020 22:25:44
User entered '0'	David Diemert (b) (4) (b) (4)	26 Sep 2020 22:25:44

US3542168
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 26 Nov 2020 09:37:10
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	26 Sep 2020 22:26:17
User entered '19 Sep 2020'	David Diemert (b) (4) (b) (4)	26 Sep 2020 22:25:44

FDA-CBER-2022-1614-6051681

US3542168
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 26 Nov 2020 09:37:10
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	26 Sep 2020 22:26:17
User entered '23 Sep 2020'	David Diemert (b) (4) (b) (4)	26 Sep 2020 22:25:44

FDA-CBER-2022-1614-6051682

US3542168
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 26 Nov 2020 09:37:10
Admitted to ICU?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	26 Sep 2020 22:26:17
User entered 'No (N)'	David Diemert (b) (4) (b) (4)	26 Sep 2020 22:25:44

FDA-CBER-2022-1614-6051683

US3542168
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 26 Nov 2020 09:37:10
Number of Days in ICU

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	26 Sep 2020 22:26:17
User entered empty.	David Diemert (b) (4) (b) (4)	26 Sep 2020 22:25:44

FDA-CBER-2022-1614-6051684

US3542168
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 26 Nov 2020 09:37:10
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	26 Sep 2020 22:26:17
User entered '0'	David Diemert (b) (4) (b) (4)	26 Sep 2020 22:25:44

FDA-CBER-2022-1614-6051685

US3542168
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 26 Nov 2020 09:37:10
Congenital anomaly or birth defect

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	26 Sep 2020 22:26:17
User entered '0'	David Diemert (b) (4) (b) (4)	26 Sep 2020 22:25:44

FDA-CBER-2022-1614-6051686

US3542168
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 26 Nov 2020 09:37:10
Other medically important event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	26 Sep 2020 22:26:17
User entered '0'	David Diemert (b) (4) (b) (4)	26 Sep 2020 22:25:44

FDA-CBER-2022-1614-6051687

US3542168
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 26 Nov 2020 09:37:10
Relationship to investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	26 Sep 2020 22:26:17
User entered 'Not Related (NOT RELATED)'	David Diemert (b) (4) (b) (4)	26 Sep 2020 22:25:44

FDA-CBER-2022-1614-6051688

US3542168
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 26 Nov 2020 09:37:10
Relationship to Study Procedure

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	26 Sep 2020 22:26:17
User entered 'Not Related (NOT RELATED)'	David Diemert (b) (4) (b) (4)	26 Sep 2020 22:25:44

FDA-CBER-2022-1614-6051689

US3542168
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 26 Nov 2020 09:37:10
Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:22:03
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	23 Nov 2020 08:32:48
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered with 'Primary reason for Dosing Discontinuation, as recorded on the Exposure eCRF for Visit 2, HAS been listed as due to AE. Please verify.' (Site from System).	David Diemert (b) (4) (b) (4)	21 Nov 2020 22:17:50
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	21 Nov 2020 22:15:12
DataPoint Un-verified.	David Diemert (b) (4) (b) (4)	21 Nov 2020 22:15:12
Signature has been broken.	David Diemert (b) (4) (b) (4)	21 Nov 2020 22:15:12
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: New Information	David Diemert (b) (4) (b) (4)	21 Nov 2020 22:15:12
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	26 Sep 2020 22:26:17
User entered 'None (NONE)'	David Diemert (b) (4) (b) (4)	26 Sep 2020 22:25:44

FDA-CBER-2022-1614-6051690

US3542168
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 26 Nov 2020 09:37:10
None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	26 Sep 2020 22:26:17
User entered '0'	David Diemert (b) (4) (b) (4)	26 Sep 2020 22:25:44

FDA-CBER-2022-1614-6051691

US3542168
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 26 Nov 2020 09:37:10
Concomitant Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	26 Sep 2020 22:26:17
User entered '1'	David Diemert (b) (4) (b) (4)	26 Sep 2020 22:25:44

FDA-CBER-2022-1614-6051692

US3542168
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 26 Nov 2020 09:37:10
Concomitant Procedure

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	26 Sep 2020 22:26:17
User entered '0'	David Diemert (b) (4) (b) (4)	26 Sep 2020 22:25:44

FDA-CBER-2022-1614-6051693

US3542168
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 26 Nov 2020 09:37:10
Outcome

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	26 Sep 2020 22:26:17
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	David Diemert (b) (4) (b) (4)	26 Sep 2020 22:25:44

FDA-CBER-2022-1614-6051694

US3542168
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 26 Nov 2020 09:37:10
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	26 Sep 2020 22:26:17
User entered empty.	David Diemert (b) (4) (b) (4)	26 Sep 2020 22:25:44

FDA-CBER-2022-1614-6051695

US3542168
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 26 Nov 2020 09:37:10
Narrative

Audit	User	Time (GMT)
Query 'Please verify if patient diagnosed with Borderline Personality Disorder in hospital. Per medical history start date is UN/UNK/2000.' canceled (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 17:12:52
User opened query 'Please verify if patient diagnosed with Borderline Personality Disorder in hospital. Per medical history start date is UN/UNK/2000.' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 17:12:34
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	28 Oct 2020 18:06:06
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'Not currently available.' (Site from Safety).	David Diemert (b) (4) (b) (4)	27 Oct 2020 20:24:27
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	06 Oct 2020 12:06:30
User signature succeeded.	David Diemert (b) (4) (b) (4)	26 Sep 2020 22:26:17
User entered 'Participant called study team on 24SEP2020 to report that he had been re-admitted to the psychiatric ward of a local hospital on 19SEP2020 due to recurrence of symptoms of severe anxiety. While in hospital he was diagnosed with borderline personality disorder and started on both lithium and mirtazipine, with improvement of symptoms. He was discharged on 23SEP2020 with follow-up planned with outpatient psychiatry.'	David Diemert (b) (4) (b) (4)	26 Sep 2020 22:25:44

FDA-CBER-2022-1614-6051696

US3542168
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 26 Nov 2020 09:37:10
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '1'	System	26 Sep 2020 22:25:44

FDA-CBER-2022-1614-6051697

US3542168
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 26 Nov 2020 09:37:10
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	26 Sep 2020 22:25:44

FDA-CBER-2022-1614-6051698

US3542168
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 26 Nov 2020 09:37:10
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	26 Sep 2020 22:25:44

FDA-CBER-2022-1614-6051699

US3542168
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 26 Nov 2020 09:37:10
AEID

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 17:32:35
User entered 'USA-US084-2020-mRNA-1273-P301000001'	(b) (4), (b) (6)	30 Sep 2020 17:32:26

FDA-CBER-2022-1614-6051700

US3542168
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 26 Nov 2020 09:37:10
Adverse event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression aggravated - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Sep 2020 15:18:56
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Sep 2020 15:18:56
Data point term sent to Coder	System	30 Sep 2020 14:55:02
User entered 'depression exacerbation'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:54:24

FDA-CBER-2022-1614-6051701

US3542168
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 26 Nov 2020 09:37:10
Was this a medically-attended AE?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered 'Yes (Y)'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:54:24

FDA-CBER-2022-1614-6051702

US3542168
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 26 Nov 2020 09:37:10
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered 'No (N)'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:54:24

FDA-CBER-2022-1614-6051703

US3542168
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 26 Nov 2020 09:37:10
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered 'No (N)'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:54:24

FDA-CBER-2022-1614-6051704

US3542168
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 26 Nov 2020 09:37:10
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered '19 Sep 2020'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:54:24

FDA-CBER-2022-1614-6051705

US3542168
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 26 Nov 2020 09:37:10
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered empty.	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:54:24

FDA-CBER-2022-1614-6051706

US3542168
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 26 Nov 2020 09:37:10
AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 14:54:24

FDA-CBER-2022-1614-6051707

US3542168
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 26 Nov 2020 09:37:10
Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered 'No (N)'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:54:24

FDA-CBER-2022-1614-6051708

US3542168
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 26 Nov 2020 09:37:10
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered '23 Sep 2020'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:54:24

FDA-CBER-2022-1614-6051709

US3542168
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 26 Nov 2020 09:37:10
End time *(00:00-23:59)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered empty.	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:54:24

FDA-CBER-2022-1614-6051710

US3542168
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 26 Nov 2020 09:37:10
AE End Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 14:54:24

FDA-CBER-2022-1614-6051711

US3542168
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 26 Nov 2020 09:37:10
Severity

Audit	User	Time (GMT)
User closed query 'PV Query: Please consider updating severity of event of depression to grade 4.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 17:27:30
Query 'PV Query: Please consider updating severity of event of depression to grade 4.' answered with 'Depression was not Grade 4. It was not the primary reason for the admission.' (Site from Safety).	David Diemert (b) (4) (b) (4)	12 Nov 2020 22:11:26
User opened query 'PV Query: Please consider updating severity of event of depression to grade 4.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 01:49:16
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered 'Grade 3/Severe (Grade 3/Severe)'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:54:24

FDA-CBER-2022-1614-6051712

US3542168
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 26 Nov 2020 09:37:10
Is the adverse event serious?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered 'Yes (Y)'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:54:24

FDA-CBER-2022-1614-6051713

US3542168
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 26 Nov 2020 09:37:10
Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered '0'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:54:24

US3542168
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 26 Nov 2020 09:37:10
Life threatening

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered '0'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:54:24

FDA-CBER-2022-1614-6051715

US3542168
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 26 Nov 2020 09:37:10
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered '1'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:54:24

FDA-CBER-2022-1614-6051716

US3542168
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 26 Nov 2020 09:37:10
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered '19 Sep 2020'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:54:24

FDA-CBER-2022-1614-6051717

US3542168
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 26 Nov 2020 09:37:10
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered '23 Sep 2020'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:54:24

FDA-CBER-2022-1614-6051718

US3542168
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 26 Nov 2020 09:37:10
Admitted to ICU?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered 'No (N)'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:54:24

FDA-CBER-2022-1614-6051719

US3542168
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 26 Nov 2020 09:37:10
Number of Days in ICU

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered empty.	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:54:24

FDA-CBER-2022-1614-6051720

US3542168
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 26 Nov 2020 09:37:10
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered '0'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:54:24

FDA-CBER-2022-1614-6051721

US3542168
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 26 Nov 2020 09:37:10
Congenital anomaly or birth defect

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered '0'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:54:24

US3542168
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 26 Nov 2020 09:37:10
Other medically important event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered '0'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:54:24

FDA-CBER-2022-1614-6051723

US3542168
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 26 Nov 2020 09:37:10
Relationship to investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered 'Not Related (NOT RELATED)'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:54:24

FDA-CBER-2022-1614-6051724

US3542168
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 26 Nov 2020 09:37:10
Relationship to Study Procedure

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered 'Not Related (NOT RELATED)'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:54:24

FDA-CBER-2022-1614-6051725

US3542168
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 26 Nov 2020 09:37:10
Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered 'None (NONE)'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:54:24

FDA-CBER-2022-1614-6051726

US3542168
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 26 Nov 2020 09:37:10
None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered '0'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:54:24

FDA-CBER-2022-1614-6051727

US3542168
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 26 Nov 2020 09:37:10
Concomitant Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered '1'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:54:24

FDA-CBER-2022-1614-6051728

US3542168
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 26 Nov 2020 09:37:10
Concomitant Procedure

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered '0'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:54:24

FDA-CBER-2022-1614-6051729

US3542168
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 26 Nov 2020 09:37:10
Outcome

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:54:24

FDA-CBER-2022-1614-6051730

US3542168
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 26 Nov 2020 09:37:10
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered empty.	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:54:24

FDA-CBER-2022-1614-6051731

US3542168
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 26 Nov 2020 09:37:10
Narrative

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	30 Sep 2020 15:04:41
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	30 Sep 2020 15:04:41
User entered 'Participant went to emergency department to be treated for lower leg pain, thought to be attributed to sickle cell disease. He was then admitted to the psych department for exacerbation of chronic anxiety and depression. He was diagnosed with PTSD and borderline personality disorder and given medication for treatment.' reason for change: Data Entry Error	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 15:04:41
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	30 Sep 2020 14:54:24
User entered empty.	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:54:24

FDA-CBER-2022-1614-6051732

US3542168
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 26 Nov 2020 09:37:10
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '1'	System	30 Sep 2020 14:54:24

FDA-CBER-2022-1614-6051733

US3542168
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 26 Nov 2020 09:37:10
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	30 Sep 2020 14:54:24

FDA-CBER-2022-1614-6051734

US3542168
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 26 Nov 2020 09:37:10
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	30 Sep 2020 14:54:24

FDA-CBER-2022-1614-6051735

US3542168
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 26 Nov 2020 09:37:10
Adverse event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
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: Pain in extremity, LLT: Leg pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Sep 2020 15:32:52
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Sep 2020 15:32:52
Data point term sent to Coder	System	30 Sep 2020 14:56:04
User entered 'lower leg pain'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:55:14

US3542168
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 26 Nov 2020 09:37:10
Was this a medically-attended AE?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered 'Yes (Y)'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:55:14

FDA-CBER-2022-1614-6051737

US3542168
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 26 Nov 2020 09:37:10
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered 'No (N)'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:55:14

FDA-CBER-2022-1614-6051738

US3542168
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 26 Nov 2020 09:37:10
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered 'No (N)'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:55:14

FDA-CBER-2022-1614-6051739

US3542168
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 26 Nov 2020 09:37:10
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered '18 Sep 2020'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:55:14

FDA-CBER-2022-1614-6051740

US3542168
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 26 Nov 2020 09:37:10
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered empty.	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:55:14

FDA-CBER-2022-1614-6051741

US3542168
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 26 Nov 2020 09:37:10
AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 14:55:14

FDA-CBER-2022-1614-6051742

US3542168
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 26 Nov 2020 09:37:10
Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered 'No (N)'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:55:14

FDA-CBER-2022-1614-6051743

US3542168
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 26 Nov 2020 09:37:10
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered '19 Sep 2020'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:55:14

FDA-CBER-2022-1614-6051744

US3542168
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 26 Nov 2020 09:37:10
End time *(00:00-23:59)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered empty.	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:55:14

FDA-CBER-2022-1614-6051745

US3542168
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 26 Nov 2020 09:37:10
AE End Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 14:55:14

FDA-CBER-2022-1614-6051746

US3542168
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 26 Nov 2020 09:37:10
Severity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:55:14

FDA-CBER-2022-1614-6051747

US3542168
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 26 Nov 2020 09:37:10
Is the adverse event serious?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered 'No (N)'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:55:14

FDA-CBER-2022-1614-6051748

US3542168
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 26 Nov 2020 09:37:10
Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered '0'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:55:14

FDA-CBER-2022-1614-6051749

US3542168
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 26 Nov 2020 09:37:10
Life threatening

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered '0'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:55:14

FDA-CBER-2022-1614-6051750

US3542168
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 26 Nov 2020 09:37:10
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered '0'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:55:14

US3542168
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 26 Nov 2020 09:37:10
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered empty.	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:55:14

FDA-CBER-2022-1614-6051752

US3542168
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 26 Nov 2020 09:37:10
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered empty.	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:55:14

FDA-CBER-2022-1614-6051753

US3542168
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 26 Nov 2020 09:37:10
Admitted to ICU?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered empty.	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:55:14

FDA-CBER-2022-1614-6051754

US3542168
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 26 Nov 2020 09:37:10
Number of Days in ICU

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered empty.	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:55:14

FDA-CBER-2022-1614-6051755

US3542168
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 26 Nov 2020 09:37:10
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered '0'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:55:14

FDA-CBER-2022-1614-6051756

US3542168
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 26 Nov 2020 09:37:10
Congenital anomaly or birth defect

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered '0'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:55:14

FDA-CBER-2022-1614-6051757

US3542168
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 26 Nov 2020 09:37:10
Other medically important event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered '0'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:55:14

FDA-CBER-2022-1614-6051758

US3542168
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 26 Nov 2020 09:37:10
Relationship to investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered 'Not Related (NOT RELATED)'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:55:14

FDA-CBER-2022-1614-6051759

US3542168
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 26 Nov 2020 09:37:10
Relationship to Study Procedure

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered 'Not Related (NOT RELATED)'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:55:14

FDA-CBER-2022-1614-6051760

US3542168
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 26 Nov 2020 09:37:10
Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered 'None (NONE)'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:55:14

FDA-CBER-2022-1614-6051761

US3542168
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 26 Nov 2020 09:37:10
None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered '0'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:55:14

FDA-CBER-2022-1614-6051762

US3542168
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 26 Nov 2020 09:37:10
Concomitant Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered '1'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:55:14

FDA-CBER-2022-1614-6051763

US3542168
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 26 Nov 2020 09:37:10
Concomitant Procedure

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered '0'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:55:14

FDA-CBER-2022-1614-6051764

US3542168
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 26 Nov 2020 09:37:10
Outcome

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:55:14

FDA-CBER-2022-1614-6051765

US3542168
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 26 Nov 2020 09:37:10
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered empty.	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:55:14

FDA-CBER-2022-1614-6051766

US3542168
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 26 Nov 2020 09:37:10
Narrative

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:20:24
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered empty.	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:55:14

FDA-CBER-2022-1614-6051767

US3542168
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 26 Nov 2020 09:37:10
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '0'	System	30 Sep 2020 14:55:14

FDA-CBER-2022-1614-6051768

US3542168
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 26 Nov 2020 09:37:10
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	30 Sep 2020 14:55:14

FDA-CBER-2022-1614-6051769

US3542168
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 26 Nov 2020 09:37:10
Adverse event

Audit	User	Time (GMT)
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory tract signs and symptoms, HLT: Upper respiratory tract signs and symptoms, PT: Rhinorrhoea, LLT: Rhinorrhea - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 11:33:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 11:33:11
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:24:13
Data point term sent to Coder	System	02 Nov 2020 19:56:29
User entered 'Rhinorrhea'	Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:04

FDA-CBER-2022-1614-6051770

US3542168
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 26 Nov 2020 09:37:10
Was this a medically-attended AE?

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:24:13
User entered 'No (N)'	Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:04

FDA-CBER-2022-1614-6051771

US3542168
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 26 Nov 2020 09:37:10
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:24:13
User entered 'No (N)'	Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:04

FDA-CBER-2022-1614-6051772

US3542168
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 26 Nov 2020 09:37:10
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:24:13
User entered 'No (N)'	Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:04

FDA-CBER-2022-1614-6051773

US3542168
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 26 Nov 2020 09:37:10
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:24:13
User entered '21 Oct 2020'	Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:04

FDA-CBER-2022-1614-6051774

US3542168
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 26 Nov 2020 09:37:10
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:24:13
User entered empty.	Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:04

FDA-CBER-2022-1614-6051775

US3542168
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 26 Nov 2020 09:37:10
AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	02 Nov 2020 19:56:04

FDA-CBER-2022-1614-6051776

US3542168
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 26 Nov 2020 09:37:10
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:24:13
User entered 'No (N)'	Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:04

FDA-CBER-2022-1614-6051777

US3542168
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 26 Nov 2020 09:37:10
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:24:13
User entered '23 Oct 2020'	Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:04

FDA-CBER-2022-1614-6051778

US3542168
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 26 Nov 2020 09:37:10
End time *(00:00-23:59)*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:24:13
User entered empty.	Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:04

FDA-CBER-2022-1614-6051779

US3542168
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 26 Nov 2020 09:37:10
AE End Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	02 Nov 2020 19:56:04

FDA-CBER-2022-1614-6051780

US3542168
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 26 Nov 2020 09:37:10
Severity

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:24:13
User entered 'Grade 1/Mild (Grade 1/Mild)'	Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:04

FDA-CBER-2022-1614-6051781

US3542168
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 26 Nov 2020 09:37:10
Is the adverse event serious?

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:24:13
User entered 'No (N)'	Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:04

FDA-CBER-2022-1614-6051782

US3542168
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 26 Nov 2020 09:37:10
Death

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:24:13
User entered '0'	Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:04

FDA-CBER-2022-1614-6051783

US3542168
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 26 Nov 2020 09:37:10
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:24:13
User entered '0'	Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:04

FDA-CBER-2022-1614-6051784

US3542168
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 26 Nov 2020 09:37:10
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:24:13
User entered '0'	Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:04

FDA-CBER-2022-1614-6051785

US3542168
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 26 Nov 2020 09:37:10
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:24:13
User entered empty.	Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:04

FDA-CBER-2022-1614-6051786

US3542168
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 26 Nov 2020 09:37:10
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:24:13
User entered empty.	Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:04

FDA-CBER-2022-1614-6051787

US3542168
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 26 Nov 2020 09:37:10
Admitted to ICU?

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:24:13
User entered empty.	Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:04

FDA-CBER-2022-1614-6051788

US3542168
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 26 Nov 2020 09:37:10
Number of Days in ICU

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:24:13
User entered empty.	Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:04

FDA-CBER-2022-1614-6051789

US3542168
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 26 Nov 2020 09:37:10
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:24:13
User entered '0'	Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:04

FDA-CBER-2022-1614-6051790

US3542168
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 26 Nov 2020 09:37:10
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:24:13
User entered '0'	Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:04

FDA-CBER-2022-1614-6051791

US3542168
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 26 Nov 2020 09:37:10
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:24:13
User entered '0'	Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:04

FDA-CBER-2022-1614-6051792

US3542168
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 26 Nov 2020 09:37:10
Relationship to investigational product

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:24:13
User entered 'Not Related (NOT RELATED)'	Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:04

FDA-CBER-2022-1614-6051793

US3542168
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 26 Nov 2020 09:37:10
Relationship to Study Procedure

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:24:13
User entered 'Not Related (NOT RELATED)'	Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:04

FDA-CBER-2022-1614-6051794

US3542168
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 26 Nov 2020 09:37:10
Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:24:13
User entered 'None (NONE)'	Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:04

FDA-CBER-2022-1614-6051795

US3542168
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 26 Nov 2020 09:37:10
None

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:24:13
User entered '1'	Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:04

FDA-CBER-2022-1614-6051796

US3542168
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 26 Nov 2020 09:37:10
Concomitant Medication

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:24:13
User entered '0'	Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:04

FDA-CBER-2022-1614-6051797

US3542168
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 26 Nov 2020 09:37:10
Concomitant Procedure

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:24:13
User entered '0'	Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:04

FDA-CBER-2022-1614-6051798

US3542168
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 26 Nov 2020 09:37:10
Outcome

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:24:13
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:04

FDA-CBER-2022-1614-6051799

US3542168
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 26 Nov 2020 09:37:10
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:24:13
User entered empty.	Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:04

FDA-CBER-2022-1614-6051800

US3542168
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 26 Nov 2020 09:37:10
Narrative

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:24:13
User entered empty.	Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:04

FDA-CBER-2022-1614-6051801

US3542168
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 26 Nov 2020 09:37:10
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '0'	System	02 Nov 2020 19:56:04

FDA-CBER-2022-1614-6051802

US3542168
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 26 Nov 2020 09:37:10
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	02 Nov 2020 19:56:04

FDA-CBER-2022-1614-6051803

US3542168
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 26 Nov 2020 09:37:10
Adverse event

Audit	User	Time (GMT)
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 11:37:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 11:37:03
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:24:13
Data point term sent to Coder	System	02 Nov 2020 19:57:29
User entered 'Headache'	Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:53

FDA-CBER-2022-1614-6051804

US3542168
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 26 Nov 2020 09:37:10
Was this a medically-attended AE?

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:24:13
User entered 'No (N)'	Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:53

FDA-CBER-2022-1614-6051805

US3542168
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 26 Nov 2020 09:37:10
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:24:13
User entered 'No (N)'	Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:53

FDA-CBER-2022-1614-6051806

US3542168
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 26 Nov 2020 09:37:10
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:24:13
User entered 'No (N)'	Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:53

FDA-CBER-2022-1614-6051807

US3542168
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 26 Nov 2020 09:37:10
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:24:13
User entered '21 Oct 2020'	Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:53

FDA-CBER-2022-1614-6051808

US3542168
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 26 Nov 2020 09:37:10
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:24:13
User entered empty.	Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:53

FDA-CBER-2022-1614-6051809

US3542168
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 26 Nov 2020 09:37:10
AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	02 Nov 2020 19:56:53

FDA-CBER-2022-1614-6051810

US3542168
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 26 Nov 2020 09:37:10
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:24:13
User entered 'No (N)'	Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:53

FDA-CBER-2022-1614-6051811

US3542168
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 26 Nov 2020 09:37:10
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:24:13
User entered '23 Oct 2020'	Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:53

FDA-CBER-2022-1614-6051812

US3542168
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 26 Nov 2020 09:37:10
End time *(00:00-23:59)*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:24:13
User entered empty.	Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:53

FDA-CBER-2022-1614-6051813

US3542168
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 26 Nov 2020 09:37:10
AE End Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	02 Nov 2020 19:56:53

FDA-CBER-2022-1614-6051814

US3542168
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 26 Nov 2020 09:37:10
Severity

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:24:13
User entered 'Grade 1/Mild (Grade 1/Mild)'	Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:53

FDA-CBER-2022-1614-6051815

US3542168
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 26 Nov 2020 09:37:10
Is the adverse event serious?

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:24:13
User entered 'No (N)'	Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:53

FDA-CBER-2022-1614-6051816

US3542168
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 26 Nov 2020 09:37:10
Death

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:24:13
User entered '0'	Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:53

FDA-CBER-2022-1614-6051817

US3542168
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 26 Nov 2020 09:37:10
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:24:13
User entered '0'	Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:53

FDA-CBER-2022-1614-6051818

US3542168
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 26 Nov 2020 09:37:10
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:24:13
User entered '0'	Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:53

FDA-CBER-2022-1614-6051819

US3542168
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 26 Nov 2020 09:37:10
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:24:13
User entered empty.	Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:53

FDA-CBER-2022-1614-6051820

US3542168
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 26 Nov 2020 09:37:10
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:24:13
User entered empty.	Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:53

FDA-CBER-2022-1614-6051821

US3542168
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 26 Nov 2020 09:37:10
Admitted to ICU?

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:24:13
User entered empty.	Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:53

FDA-CBER-2022-1614-6051822

US3542168
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 26 Nov 2020 09:37:10
Number of Days in ICU

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:24:13
User entered empty.	Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:53

FDA-CBER-2022-1614-6051823

US3542168
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 26 Nov 2020 09:37:10
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:24:13
User entered '0'	Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:53

FDA-CBER-2022-1614-6051824

US3542168
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 26 Nov 2020 09:37:10
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:24:13
User entered '0'	Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:53

FDA-CBER-2022-1614-6051825

US3542168
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 26 Nov 2020 09:37:10
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:24:13
User entered '0'	Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:53

FDA-CBER-2022-1614-6051826

US3542168
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 26 Nov 2020 09:37:10
Relationship to investigational product

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:24:13
User entered 'Not Related (NOT RELATED)'	Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:53

FDA-CBER-2022-1614-6051827

US3542168
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 26 Nov 2020 09:37:10
Relationship to Study Procedure

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:24:13
User entered 'Not Related (NOT RELATED)'	Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:53

FDA-CBER-2022-1614-6051828

US3542168
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 26 Nov 2020 09:37:10
Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:24:13
User entered 'None (NONE)'	Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:53

FDA-CBER-2022-1614-6051829

US3542168
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 26 Nov 2020 09:37:10
None

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:24:13
User entered '0'	Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:53

FDA-CBER-2022-1614-6051830

US3542168
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 26 Nov 2020 09:37:10
Concomitant Medication

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:24:13
User entered '1'	Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:53

FDA-CBER-2022-1614-6051831

US3542168
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 26 Nov 2020 09:37:10
Concomitant Procedure

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:24:13
User entered '0'	Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:53

FDA-CBER-2022-1614-6051832

US3542168
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 26 Nov 2020 09:37:10
Outcome

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:24:13
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:53

FDA-CBER-2022-1614-6051833

US3542168
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 26 Nov 2020 09:37:10
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:24:13
User entered empty.	Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:53

FDA-CBER-2022-1614-6051834

US3542168
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 26 Nov 2020 09:37:10
Narrative

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	03 Nov 2020 21:24:13
User entered empty.	Erika Faust (b) (4) (b) (4)	02 Nov 2020 19:56:53

FDA-CBER-2022-1614-6051835

US3542168
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 26 Nov 2020 09:37:10
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '0'	System	02 Nov 2020 19:56:53

FDA-CBER-2022-1614-6051836

US3542168
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 26 Nov 2020 09:37:10
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	02 Nov 2020 19:56:53

FDA-CBER-2022-1614-6051837

US3542168
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 26 Nov 2020 09:37:10
Adverse event

Audit	User	Time (GMT)
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Muscle, tendon and ligament injuries, PT: Muscle strain, LLT: Muscle strain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Nov 2020 23:21:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Nov 2020 23:21:41
Data point term sent to Coder	System	13 Nov 2020 17:32:02
User entered 'Right trapezius strain'	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:31:19

US3542168
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 26 Nov 2020 09:37:10
Was this a medically-attended AE?

Audit	User	Time (GMT)
User entered 'No (N)'	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:31:19

FDA-CBER-2022-1614-6051839

US3542168
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 26 Nov 2020 09:37:10
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
User entered 'No (N)'	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:31:19

FDA-CBER-2022-1614-6051840

US3542168
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 26 Nov 2020 09:37:10
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
User entered 'No (N)'	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:31:19

FDA-CBER-2022-1614-6051841

US3542168
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 26 Nov 2020 09:37:10
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered '10 Nov 2020'	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:31:19

FDA-CBER-2022-1614-6051842

US3542168
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 26 Nov 2020 09:37:10
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
User entered empty.	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:31:19

FDA-CBER-2022-1614-6051843

US3542168
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 26 Nov 2020 09:37:10
AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 17:31:19

FDA-CBER-2022-1614-6051844

US3542168
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 26 Nov 2020 09:37:10
Ongoing?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:31:19

FDA-CBER-2022-1614-6051845

US3542168
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 26 Nov 2020 09:37:10
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered empty.	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:31:19

FDA-CBER-2022-1614-6051846

US3542168
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 26 Nov 2020 09:37:10
End time *(00:00-23:59)*

Audit	User	Time (GMT)
User entered empty.	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:31:19

FDA-CBER-2022-1614-6051847

US3542168
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 26 Nov 2020 09:37:10
AE End Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 17:31:19

FDA-CBER-2022-1614-6051848

US3542168
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 26 Nov 2020 09:37:10
Severity

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:31:19

FDA-CBER-2022-1614-6051849

US3542168
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 26 Nov 2020 09:37:10
Is the adverse event serious?

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Nov 2020 17:31:28
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Nov 2020 17:31:28
User entered 'No (N)' reason for change: Data Entry Error	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:31:28
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Nov 2020 17:31:19
User entered empty.	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:31:19

FDA-CBER-2022-1614-6051850

US3542168
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 26 Nov 2020 09:37:10
Death

Audit	User	Time (GMT)
User entered '0'	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:31:19

FDA-CBER-2022-1614-6051851

US3542168
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 26 Nov 2020 09:37:10
Life threatening

Audit	User	Time (GMT)
User entered '0'	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:31:19

FDA-CBER-2022-1614-6051852

US3542168
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 26 Nov 2020 09:37:10
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User entered '0'	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:31:19

FDA-CBER-2022-1614-6051853

US3542168
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 26 Nov 2020 09:37:10
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered empty.	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:31:19

FDA-CBER-2022-1614-6051854

US3542168
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 26 Nov 2020 09:37:10
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User entered empty.	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:31:19

FDA-CBER-2022-1614-6051855

US3542168
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 26 Nov 2020 09:37:10
Admitted to ICU?

Audit	User	Time (GMT)
User entered empty.	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:31:19

FDA-CBER-2022-1614-6051856

US3542168
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 26 Nov 2020 09:37:10
Number of Days in ICU

Audit	User	Time (GMT)
User entered empty.	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:31:19

FDA-CBER-2022-1614-6051857

US3542168
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 26 Nov 2020 09:37:10
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User entered '0'	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:31:19

FDA-CBER-2022-1614-6051858

US3542168
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 26 Nov 2020 09:37:10
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User entered '0'	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:31:19

FDA-CBER-2022-1614-6051859

US3542168
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 26 Nov 2020 09:37:10
Other medically important event

Audit	User	Time (GMT)
User entered '0'	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:31:19

FDA-CBER-2022-1614-6051860

US3542168
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 26 Nov 2020 09:37:10
Relationship to investigational product

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:31:19

FDA-CBER-2022-1614-6051861

US3542168
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 26 Nov 2020 09:37:10
Relationship to Study Procedure

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:31:19

FDA-CBER-2022-1614-6051862

US3542168
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 26 Nov 2020 09:37:10
Action taken with investigational product

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:31:19

FDA-CBER-2022-1614-6051863

US3542168
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 26 Nov 2020 09:37:10
None

Audit	User	Time (GMT)
User entered '0'	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:31:19

FDA-CBER-2022-1614-6051864

US3542168
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 26 Nov 2020 09:37:10
Concomitant Medication

Audit	User	Time (GMT)
User entered '1'	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:31:19

FDA-CBER-2022-1614-6051865

US3542168
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 26 Nov 2020 09:37:10
Concomitant Procedure

Audit	User	Time (GMT)
User entered '0'	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:31:19

FDA-CBER-2022-1614-6051866

US3542168
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 26 Nov 2020 09:37:10
Outcome

Audit	User	Time (GMT)
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:31:19

FDA-CBER-2022-1614-6051867

US3542168
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 26 Nov 2020 09:37:10
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:31:19

FDA-CBER-2022-1614-6051868

US3542168
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 26 Nov 2020 09:37:10
Narrative

Audit	User	Time (GMT)
User entered empty.	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:31:19

FDA-CBER-2022-1614-6051869

US3542168
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 26 Nov 2020 09:37:10
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '0'	System	13 Nov 2020 17:31:28

FDA-CBER-2022-1614-6051870

US3542168
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 26 Nov 2020 09:37:10
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	13 Nov 2020 17:31:19

FDA-CBER-2022-1614-6051871

US3542168

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:37:10

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:20:09
User closed query 'Per ETRTR: Please confirm Medication, dates and dosing of ConMeds provided at hospitalization for SAE Anxiety, thanks.' (Site from CRA).	(b) (4), (b) (6)	15 Nov 2020 21:07:29
Query 'Per ETRTR: Please confirm Medication, dates and dosing of ConMeds provided at hospitalization for SAE Anxiety, thanks.' answered with 'This was already done. Why is this being queried?' (Site from CRA).	David Diemert (b) (4) (b) (4)	27 Oct 2020 20:25:58
User opened query 'Per ETRTR: Please confirm Medication, dates and dosing of ConMeds provided at hospitalization for SAE Anxiety, thanks.' (Site from CRA).	(b) (4), (b) (6)	24 Sep 2020 20:53:42
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered 'Yes (Y)'	Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:48:41

FDA-CBER-2022-1614-6051872

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 26 Nov 2020 09:37:10
Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 18:50:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 18:50:55
Data point term sent to Coder	System	21 Sep 2020 18:49:35
User entered 'lisinopril'	Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:49:08

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 26 Nov 2020 09:37:10
Prophylaxis

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered 'No (N)'	Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:49:08

FDA-CBER-2022-1614-6051874

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 26 Nov 2020 09:37:10
Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered 'hypertension'	Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:49:08

FDA-CBER-2022-1614-6051875

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 26 Nov 2020 09:37:10
Dose per administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered '20'	Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:49:08

FDA-CBER-2022-1614-6051876

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 26 Nov 2020 09:37:10
Dose unit

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered 'mg (mg)'	Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:49:08

FDA-CBER-2022-1614-6051877

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 26 Nov 2020 09:37:10
If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered empty.	Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:49:08

FDA-CBER-2022-1614-6051878

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 26 Nov 2020 09:37:10
Frequency

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered 'once daily (QD)'	Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:49:08

FDA-CBER-2022-1614-6051879

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 26 Nov 2020 09:37:10
If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered empty.	Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:49:08

FDA-CBER-2022-1614-6051880

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 26 Nov 2020 09:37:10
Route of administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered 'Oral (ORAL)'	Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:49:08

FDA-CBER-2022-1614-6051881

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 26 Nov 2020 09:37:10
If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered empty.	Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:49:08

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 26 Nov 2020 09:37:10
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered 'un UNK 2018'	Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:49:08

FDA-CBER-2022-1614-6051883

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 26 Nov 2020 09:37:10
Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered '0'	Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:49:08

FDA-CBER-2022-1614-6051884

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 26 Nov 2020 09:37:10
Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered 'Yes (Y)'	Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:49:08

FDA-CBER-2022-1614-6051885

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 26 Nov 2020 09:37:10
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered empty.	Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:49:08

FDA-CBER-2022-1614-6051886

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 26 Nov 2020 09:37:10
Was this medication taken for solicited event?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered 'No (N)'	Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:49:08

FDA-CBER-2022-1614-6051887

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 26 Nov 2020 09:37:10
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 18:49:08

FDA-CBER-2022-1614-6051888

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 26 Nov 2020 09:37:10
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 18:49:08

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 26 Nov 2020 09:37:10
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Sep 2020 18:49:08

FDA-CBER-2022-1614-6051890

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 26 Nov 2020 09:37:10
Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: MIRTAZAPINE, PRODUCTSYNONYM: REMERON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 18:51:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 18:51:51
Data point term sent to Coder	System	21 Sep 2020 18:50:36
User entered 'remeron'	Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:50:01

FDA-CBER-2022-1614-6051891

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 26 Nov 2020 09:37:10
Prophylaxis

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered 'No (N)'	Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:50:01

FDA-CBER-2022-1614-6051892

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 26 Nov 2020 09:37:10
Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered 'generalized anxiety disorder'	Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:50:01

FDA-CBER-2022-1614-6051893

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 26 Nov 2020 09:37:10
Dose per administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered '15'	Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:50:01

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 26 Nov 2020 09:37:10
Dose unit

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered 'mg (mg)'	Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:50:01

FDA-CBER-2022-1614-6051895

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 26 Nov 2020 09:37:10
If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered empty.	Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:50:01

FDA-CBER-2022-1614-6051896

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 26 Nov 2020 09:37:10
Frequency

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered 'once daily (QD)'	Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:50:01

FDA-CBER-2022-1614-6051897

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 26 Nov 2020 09:37:10
If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered empty.	Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:50:01

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 26 Nov 2020 09:37:10
Route of administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered 'Oral (ORAL)'	Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:50:01

FDA-CBER-2022-1614-6051899

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 26 Nov 2020 09:37:10
If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered empty.	Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:50:01

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 26 Nov 2020 09:37:10
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered 'un UNK 2019'	Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:50:01

FDA-CBER-2022-1614-6051901

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 26 Nov 2020 09:37:10
Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered '0'	Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:50:01

FDA-CBER-2022-1614-6051902

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 26 Nov 2020 09:37:10
Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered 'No (N)'	Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:50:01

FDA-CBER-2022-1614-6051903

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 26 Nov 2020 09:37:10
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered '10 Sep 2020'	Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:50:01

FDA-CBER-2022-1614-6051904

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 26 Nov 2020 09:37:10
Was this medication taken for solicited event?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered 'No (N)'	Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:50:01

FDA-CBER-2022-1614-6051905

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 26 Nov 2020 09:37:10
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 18:50:01

FDA-CBER-2022-1614-6051906

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 26 Nov 2020 09:37:10
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 18:50:01

FDA-CBER-2022-1614-6051907

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 26 Nov 2020 09:37:10
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Sep 2020 18:50:01

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 26 Nov 2020 09:37:10
Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: MIRTAZAPINE, PRODUCTSYNONYM: REMERON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 18:51:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 18:51:51
Data point term sent to Coder	System	21 Sep 2020 18:50:36
User entered 'remeron'	Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:50:22

FDA-CBER-2022-1614-6051909

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 26 Nov 2020 09:37:10
Prophylaxis

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered 'No (N)'	Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:50:22

FDA-CBER-2022-1614-6051910

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 26 Nov 2020 09:37:10
Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered 'generalized anxiety disorder'	Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:50:22

FDA-CBER-2022-1614-6051911

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 26 Nov 2020 09:37:10
Dose per administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered '30'	Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:50:22

FDA-CBER-2022-1614-6051912

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 26 Nov 2020 09:37:10
Dose unit

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered 'mg (mg)'	Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:50:22

FDA-CBER-2022-1614-6051913

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 26 Nov 2020 09:37:10
If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered empty.	Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:50:22

FDA-CBER-2022-1614-6051914

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 26 Nov 2020 09:37:10
Frequency

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered 'once daily (QD)'	Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:50:22

FDA-CBER-2022-1614-6051915

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 26 Nov 2020 09:37:10
If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered empty.	Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:50:22

FDA-CBER-2022-1614-6051916

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 26 Nov 2020 09:37:10
Route of administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered 'Oral (ORAL)'	Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:50:22

FDA-CBER-2022-1614-6051917

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 26 Nov 2020 09:37:10
If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered empty.	Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:50:22

FDA-CBER-2022-1614-6051918

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 26 Nov 2020 09:37:10
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered '10 Sep 2020'	Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:50:22

FDA-CBER-2022-1614-6051919

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 26 Nov 2020 09:37:10
Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered '0'	Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:50:22

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 26 Nov 2020 09:37:10
Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered 'Yes (Y)'	Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:50:22

FDA-CBER-2022-1614-6051921

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 26 Nov 2020 09:37:10
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered empty.	Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:50:22

FDA-CBER-2022-1614-6051922

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 26 Nov 2020 09:37:10
Was this medication taken for solicited event?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered 'No (N)'	Taylor Ladson (b) (4) (b) (4)	21 Sep 2020 18:50:22

FDA-CBER-2022-1614-6051923

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 26 Nov 2020 09:37:10
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 18:50:22

FDA-CBER-2022-1614-6051924

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 26 Nov 2020 09:37:10
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 18:50:22

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 26 Nov 2020 09:37:10
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Sep 2020 18:50:22

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 26 Nov 2020 09:37:10
Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: MIRTAZAPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Sep 2020 14:46:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Sep 2020 14:46:48
Data point term sent to Coder	System	30 Sep 2020 14:45:47
User entered 'mirtazapine'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:45:28

FDA-CBER-2022-1614-6051927

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 26 Nov 2020 09:37:10
Prophylaxis

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered 'No (N)'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:45:28

FDA-CBER-2022-1614-6051928

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 26 Nov 2020 09:37:10
Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered 'depression'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:45:28

FDA-CBER-2022-1614-6051929

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 26 Nov 2020 09:37:10
Dose per administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered '3'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:45:28

FDA-CBER-2022-1614-6051930

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 26 Nov 2020 09:37:10
Dose unit

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered 'mg (mg)'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:45:28

FDA-CBER-2022-1614-6051931

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 26 Nov 2020 09:37:10
If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered empty.	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:45:28

FDA-CBER-2022-1614-6051932

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 26 Nov 2020 09:37:10
Frequency

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered 'once daily (QD)'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:45:28

FDA-CBER-2022-1614-6051933

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 26 Nov 2020 09:37:10
If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered empty.	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:45:28

FDA-CBER-2022-1614-6051934

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 26 Nov 2020 09:37:10
Route of administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered 'Oral (ORAL)'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:45:28

FDA-CBER-2022-1614-6051935

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 26 Nov 2020 09:37:10
If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered empty.	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:45:28

FDA-CBER-2022-1614-6051936

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 26 Nov 2020 09:37:10
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered '20 Sep 2020'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:45:28

FDA-CBER-2022-1614-6051937

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 26 Nov 2020 09:37:10
Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered '0'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:45:28

FDA-CBER-2022-1614-6051938

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 26 Nov 2020 09:37:10
Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered 'Yes (Y)'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:45:28

FDA-CBER-2022-1614-6051939

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 26 Nov 2020 09:37:10
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered empty.	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:45:28

FDA-CBER-2022-1614-6051940

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 26 Nov 2020 09:37:10
Was this medication taken for solicited event?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered 'No (N)'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:45:28

FDA-CBER-2022-1614-6051941

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 26 Nov 2020 09:37:10
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	30 Sep 2020 14:45:28

FDA-CBER-2022-1614-6051942

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 26 Nov 2020 09:37:10
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	30 Sep 2020 14:45:28

FDA-CBER-2022-1614-6051943

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 26 Nov 2020 09:37:10
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Sep 2020 14:45:28

FDA-CBER-2022-1614-6051944

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 26 Nov 2020 09:37:10
Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: LITHIUM, PRODUCT: LITHIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Sep 2020 15:32:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Sep 2020 15:32:52
Data point term sent to Coder	System	30 Sep 2020 14:47:53
User entered 'lithium'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:47:21

FDA-CBER-2022-1614-6051945

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 26 Nov 2020 09:37:10
Prophylaxis

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered 'No (N)'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:47:21

FDA-CBER-2022-1614-6051946

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 26 Nov 2020 09:37:10
Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered 'depression and anxiety'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:47:21

FDA-CBER-2022-1614-6051947

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 26 Nov 2020 09:37:10
Dose per administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered '300'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:47:21

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 26 Nov 2020 09:37:10
Dose unit

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered 'mg (mg)'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:47:21

FDA-CBER-2022-1614-6051949

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 26 Nov 2020 09:37:10
If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered empty.	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:47:21

FDA-CBER-2022-1614-6051950

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 26 Nov 2020 09:37:10
Frequency

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered 'once daily (QD)'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:47:21

FDA-CBER-2022-1614-6051951

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 26 Nov 2020 09:37:10
If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered empty.	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:47:21

FDA-CBER-2022-1614-6051952

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 26 Nov 2020 09:37:10
Route of administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered 'Oral (ORAL)'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:47:21

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 26 Nov 2020 09:37:10
If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered empty.	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:47:21

FDA-CBER-2022-1614-6051954

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 26 Nov 2020 09:37:10
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered '20 Sep 2020'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:47:21

FDA-CBER-2022-1614-6051955

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 26 Nov 2020 09:37:10
Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered '0'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:47:21

FDA-CBER-2022-1614-6051956

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 26 Nov 2020 09:37:10
Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered 'Yes (Y)'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:47:21

FDA-CBER-2022-1614-6051957

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 26 Nov 2020 09:37:10
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered empty.	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:47:21

FDA-CBER-2022-1614-6051958

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 26 Nov 2020 09:37:10
Was this medication taken for solicited event?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered 'No (N)'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:47:21

FDA-CBER-2022-1614-6051959

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 26 Nov 2020 09:37:10
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	30 Sep 2020 14:47:21

FDA-CBER-2022-1614-6051960

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 26 Nov 2020 09:37:10
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	30 Sep 2020 14:47:21

FDA-CBER-2022-1614-6051961

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 26 Nov 2020 09:37:10
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Sep 2020 14:47:21

FDA-CBER-2022-1614-6051962

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 26 Nov 2020 09:37:10
Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: ANTIHYPERTENSIVES, ATC: ANTIADRENERGIC AGENTS, PERIPHERALLY ACTING, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: PRAZOSIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Sep 2020 14:48:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Sep 2020 14:48:54
Data point term sent to Coder	System	30 Sep 2020 14:47:53
User entered 'prazosin'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:47:50

FDA-CBER-2022-1614-6051963

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 26 Nov 2020 09:37:10
Prophylaxis

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered 'No (N)'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:47:50

FDA-CBER-2022-1614-6051964

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 26 Nov 2020 09:37:10
Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered 'PTSD'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:47:50

FDA-CBER-2022-1614-6051965

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 26 Nov 2020 09:37:10
Dose per administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered '3'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:47:50

FDA-CBER-2022-1614-6051966

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 26 Nov 2020 09:37:10
Dose unit

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered 'mg (mg)'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:47:50

FDA-CBER-2022-1614-6051967

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 26 Nov 2020 09:37:10
If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered empty.	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:47:50

FDA-CBER-2022-1614-6051968

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 26 Nov 2020 09:37:10
Frequency

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered 'once daily (QD)'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:47:50

FDA-CBER-2022-1614-6051969

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 26 Nov 2020 09:37:10
If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered empty.	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:47:50

FDA-CBER-2022-1614-6051970

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 26 Nov 2020 09:37:10
Route of administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered 'Oral (ORAL)'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:47:50

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 26 Nov 2020 09:37:10
If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered empty.	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:47:50

FDA-CBER-2022-1614-6051972

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 26 Nov 2020 09:37:10
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered '20 Sep 2020'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:47:50

FDA-CBER-2022-1614-6051973

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 26 Nov 2020 09:37:10
Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered '0'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:47:50

FDA-CBER-2022-1614-6051974

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 26 Nov 2020 09:37:10
Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered 'Yes (Y)'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:47:50

FDA-CBER-2022-1614-6051975

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 26 Nov 2020 09:37:10
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered empty.	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:47:50

FDA-CBER-2022-1614-6051976

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 26 Nov 2020 09:37:10
Was this medication taken for solicited event?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered 'No (N)'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:47:50

FDA-CBER-2022-1614-6051977

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 26 Nov 2020 09:37:10
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	30 Sep 2020 14:47:50

FDA-CBER-2022-1614-6051978

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 26 Nov 2020 09:37:10
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	30 Sep 2020 14:47:50

FDA-CBER-2022-1614-6051979

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 26 Nov 2020 09:37:10
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Sep 2020 14:47:50

FDA-CBER-2022-1614-6051980

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 26 Nov 2020 09:37:10
Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User closed query 'Per MM: Please confirm this medication does not meet exclusion criteria #12 (Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening).' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 17:45:31
Query 'Per MM: Please confirm this medication does not meet exclusion criteria #12 (Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening).' answered with 'Confirmed this medication does not meet exclusion criterion #12' (Site from DM).	Elissa Malkin (b) (4) (b) (4)	20 Oct 2020 15:03:00
User opened query 'Per MM: Please confirm this medication does not meet exclusion criteria #12 (Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening).' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 14:55:08
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: OTHER HEMATOLOGICAL AGENTS, ATC: OTHER HEMATOLOGICAL AGENTS, PRODUCT: HYDROXYCARBAMIDE, PRODUCTSYNONYM: HYDROXYUREA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Sep 2020 15:22:53
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 Sep 2020 15:22:53
Data point term sent to Coder	System	30 Sep 2020 14:48:54
User entered 'HYDROXYUREA'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:48:29

FDA-CBER-2022-1614-6051981

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 26 Nov 2020 09:37:10
Prophylaxis

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered 'No (N)'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:48:29

FDA-CBER-2022-1614-6051982

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 26 Nov 2020 09:37:10
Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered 'SICKLE CELL DISEASE'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:48:29

FDA-CBER-2022-1614-6051983

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 26 Nov 2020 09:37:10
Dose per administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered '500'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:48:29

FDA-CBER-2022-1614-6051984

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 26 Nov 2020 09:37:10
Dose unit

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered 'mg (mg)'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:48:29

FDA-CBER-2022-1614-6051985

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 26 Nov 2020 09:37:10
If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered empty.	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:48:29

FDA-CBER-2022-1614-6051986

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 26 Nov 2020 09:37:10
Frequency

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered 'once daily (QD)'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:48:29

FDA-CBER-2022-1614-6051987

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 26 Nov 2020 09:37:10
If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered empty.	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:48:29

FDA-CBER-2022-1614-6051988

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 26 Nov 2020 09:37:10
Route of administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered 'Oral (ORAL)'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:48:29

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 26 Nov 2020 09:37:10
If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered empty.	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:48:29

FDA-CBER-2022-1614-6051990

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 26 Nov 2020 09:37:10
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Oct 2020 20:21:50
Signature has been broken.	David Diemert (b) (4) (b) (4)	27 Oct 2020 20:21:38
User entered 'UN May 2020' reason for change: Data Entry Error	David Diemert (b) (4) (b) (4)	27 Oct 2020 20:21:38
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered empty.	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:48:29

FDA-CBER-2022-1614-6051991

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 26 Nov 2020 09:37:10
Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	27 Oct 2020 20:21:50
Signature has been broken.	David Diemert (b) (4) (b) (4)	27 Oct 2020 20:21:38
User entered '0' reason for change: Data Entry Error	David Diemert (b) (4) (b) (4)	27 Oct 2020 20:21:38
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered '1'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:48:29

FDA-CBER-2022-1614-6051992

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 26 Nov 2020 09:37:10
Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered 'Yes (Y)'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:48:29

FDA-CBER-2022-1614-6051993

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 26 Nov 2020 09:37:10
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered empty.	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:48:29

FDA-CBER-2022-1614-6051994

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 26 Nov 2020 09:37:10
Was this medication taken for solicited event?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered 'No (N)'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:48:29

FDA-CBER-2022-1614-6051995

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 26 Nov 2020 09:37:10
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	30 Sep 2020 14:48:29

FDA-CBER-2022-1614-6051996

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 26 Nov 2020 09:37:10
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	30 Sep 2020 14:48:29

FDA-CBER-2022-1614-6051997

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 26 Nov 2020 09:37:10
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Sep 2020 14:48:29

FDA-CBER-2022-1614-6051998

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 26 Nov 2020 09:37:10
Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Sep 2020 15:36:56
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 Sep 2020 15:36:56
Data point term sent to Coder	System	30 Sep 2020 14:49:55
User entered 'morphine'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:49:03

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 26 Nov 2020 09:37:10
Prophylaxis

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered 'No (N)'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:49:03

FDA-CBER-2022-1614-6052000

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 26 Nov 2020 09:37:10
Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered 'lower leg pain'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:49:03

FDA-CBER-2022-1614-6052001

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 26 Nov 2020 09:37:10
Dose per administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered '4'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:49:03

FDA-CBER-2022-1614-6052002

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 26 Nov 2020 09:37:10
Dose unit

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered 'mg (mg)'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:49:03

FDA-CBER-2022-1614-6052003

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 26 Nov 2020 09:37:10
If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered empty.	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:49:03

FDA-CBER-2022-1614-6052004

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 26 Nov 2020 09:37:10
Frequency

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered 'once (ONCE)'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:49:03

FDA-CBER-2022-1614-6052005

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 26 Nov 2020 09:37:10
If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered empty.	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:49:03

FDA-CBER-2022-1614-6052006

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 26 Nov 2020 09:37:10
Route of administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered 'Intravenous (INTRAVENOUS)'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:49:03

FDA-CBER-2022-1614-6052007

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 26 Nov 2020 09:37:10
If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered empty.	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:49:03

FDA-CBER-2022-1614-6052008

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 26 Nov 2020 09:37:10
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered '19 Sep 2020'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:49:03

FDA-CBER-2022-1614-6052009

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 26 Nov 2020 09:37:10
Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered '0'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:49:03

FDA-CBER-2022-1614-6052010

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 26 Nov 2020 09:37:10
Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered 'No (N)'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:49:03

FDA-CBER-2022-1614-6052011

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 26 Nov 2020 09:37:10
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered '19 Sep 2020'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:49:03

FDA-CBER-2022-1614-6052012

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 26 Nov 2020 09:37:10
Was this medication taken for solicited event?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered 'No (N)'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:49:03

FDA-CBER-2022-1614-6052013

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 26 Nov 2020 09:37:10
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 14:49:03

FDA-CBER-2022-1614-6052014

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 26 Nov 2020 09:37:10
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 14:49:03

FDA-CBER-2022-1614-6052015

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 26 Nov 2020 09:37:10
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 14:49:03

FDA-CBER-2022-1614-6052016

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 26 Nov 2020 09:37:10
Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROMORPHONE HYDROCHLORIDE, PRODUCTSYNONYM: DILAUDID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Sep 2020 14:50:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Sep 2020 14:50:49
Data point term sent to Coder	System	30 Sep 2020 14:49:55
User entered 'dilaudid'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:49:49

FDA-CBER-2022-1614-6052017

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 26 Nov 2020 09:37:10
Prophylaxis

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered 'No (N)'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:49:49

FDA-CBER-2022-1614-6052018

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 26 Nov 2020 09:37:10
Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered 'lower leg pain'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:49:49

FDA-CBER-2022-1614-6052019

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 26 Nov 2020 09:37:10
Dose per administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered '1'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:49:49

FDA-CBER-2022-1614-6052020

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 26 Nov 2020 09:37:10
Dose unit

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered 'mg (mg)'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:49:49

FDA-CBER-2022-1614-6052021

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 26 Nov 2020 09:37:10
If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered empty.	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:49:49

FDA-CBER-2022-1614-6052022

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 26 Nov 2020 09:37:10
Frequency

Audit	User	Time (GMT)
User closed query 'Per subject source frequency is twice. Please verify and update if needed. ' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 15:20:51
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:20:44
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Nov 2020 04:15:40
Query 'Per subject source frequency is twice. Please verify and update if needed. ' answered with 'updated' (Site from CRA).	Elissa Malkin (b) (4) (b) (4)	17 Nov 2020 20:51:34
Signature has been broken.	Elissa Malkin (b) (4) (b) (4)	17 Nov 2020 20:51:25
User entered 'other (OTHER)' reason for change: Per Query Resolution	Elissa Malkin (b) (4) (b) (4)	17 Nov 2020 20:51:25
DataPoint Un-verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:10
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User opened query 'Per subject source frequency is twice. Please verify and update if needed. ' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 17:04:19
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered 'once (ONCE)'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:49:49

FDA-CBER-2022-1614-6052023

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 26 Nov 2020 09:37:10
If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:20:46
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Nov 2020 04:15:40
DataPoint Un-verified.	Elissa Malkin (b) (4) (b) (4)	17 Nov 2020 20:51:25
Signature has been broken.	Elissa Malkin (b) (4) (b) (4)	17 Nov 2020 20:51:25
User entered 'twice' reason for change: Per Query Resolution	Elissa Malkin (b) (4) (b) (4)	17 Nov 2020 20:51:25
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered empty.	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:49:49

FDA-CBER-2022-1614-6052024

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 26 Nov 2020 09:37:10
Route of administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered 'Intravenous (INTRAVENOUS)'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:49:49

FDA-CBER-2022-1614-6052025

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 26 Nov 2020 09:37:10
If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered empty.	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:49:49

FDA-CBER-2022-1614-6052026

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 26 Nov 2020 09:37:10
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered '19 Sep 2020'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:49:49

FDA-CBER-2022-1614-6052027

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 26 Nov 2020 09:37:10
Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered '0'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:49:49

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 26 Nov 2020 09:37:10
Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered 'No (N)'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:49:49

FDA-CBER-2022-1614-6052029

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 26 Nov 2020 09:37:10
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered '19 Sep 2020'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:49:49

FDA-CBER-2022-1614-6052030

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 26 Nov 2020 09:37:10
Was this medication taken for solicited event?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered 'No (N)'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:49:49

FDA-CBER-2022-1614-6052031

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 26 Nov 2020 09:37:10
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 14:49:49

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 26 Nov 2020 09:37:10
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 14:49:49

FDA-CBER-2022-1614-6052033

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 26 Nov 2020 09:37:10
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 14:49:49

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 26 Nov 2020 09:37:10
Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: OTHER HYPNOTICS AND SEDATIVES, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE, PRODUCTSYNONYM: BENADRYL [DIPHENHYDRAMINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Sep 2020 15:17:53
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 Sep 2020 15:17:53
Data point term sent to Coder	System	30 Sep 2020 14:50:57
User entered 'benadryl'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:50:23

FDA-CBER-2022-1614-6052035

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 26 Nov 2020 09:37:10
Prophylaxis

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered 'No (N)'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:50:23

FDA-CBER-2022-1614-6052036

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 26 Nov 2020 09:37:10
Indication

Audit	User	Time (GMT)
Query 'Please confirm indication. Benadryl not normally used for pain relief. ' canceled (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 17:14:00
DataPoint Un-verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:14
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User opened query 'Please confirm indication. Benadryl not normally used for pain relief. ' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 17:06:11
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered 'lower leg pain'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:50:23

FDA-CBER-2022-1614-6052037

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 26 Nov 2020 09:37:10
Dose per administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered '25'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:50:23

FDA-CBER-2022-1614-6052038

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 26 Nov 2020 09:37:10
Dose unit

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered 'mg (mg)'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:50:23

FDA-CBER-2022-1614-6052039

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 26 Nov 2020 09:37:10
If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered empty.	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:50:23

FDA-CBER-2022-1614-6052040

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 26 Nov 2020 09:37:10
Frequency

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered 'once (ONCE)'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:50:23

FDA-CBER-2022-1614-6052041

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 26 Nov 2020 09:37:10
If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered empty.	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:50:23

FDA-CBER-2022-1614-6052042

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 26 Nov 2020 09:37:10
Route of administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered 'Oral (ORAL)'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:50:23

FDA-CBER-2022-1614-6052043

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 26 Nov 2020 09:37:10
If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered empty.	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:50:23

FDA-CBER-2022-1614-6052044

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 26 Nov 2020 09:37:10
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered '19 Sep 2020'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:50:23

FDA-CBER-2022-1614-6052045

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 26 Nov 2020 09:37:10
Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered '0'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:50:23

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 26 Nov 2020 09:37:10
Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered 'No (N)'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:50:23

FDA-CBER-2022-1614-6052047

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 26 Nov 2020 09:37:10
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered '19 Sep 2020'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:50:23

FDA-CBER-2022-1614-6052048

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 26 Nov 2020 09:37:10
Was this medication taken for solicited event?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
User entered 'No (N)'	Taylor Ladson (b) (4) (b) (4)	30 Sep 2020 14:50:23

FDA-CBER-2022-1614-6052049

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 26 Nov 2020 09:37:10
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 14:50:23

FDA-CBER-2022-1614-6052050

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 26 Nov 2020 09:37:10
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 14:50:23

FDA-CBER-2022-1614-6052051

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 26 Nov 2020 09:37:10
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 14:50:23

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 26 Nov 2020 09:37:10
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
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)	14 Nov 2020 05:17:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Nov 2020 05:17:43
Data point term sent to Coder	System	13 Nov 2020 17:33:03
User entered 'Oxycodone'	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:32:38

FDA-CBER-2022-1614-6052053

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 26 Nov 2020 09:37:10
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User entered 'No (N)'	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:32:38

FDA-CBER-2022-1614-6052054

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 26 Nov 2020 09:37:10
Indication

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User entered 'Sickle cell disease'	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:32:38

FDA-CBER-2022-1614-6052055

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 26 Nov 2020 09:37:10
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User entered '10'	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:32:38

FDA-CBER-2022-1614-6052056

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 26 Nov 2020 09:37:10
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User entered 'mg (mg)'	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:32:38

FDA-CBER-2022-1614-6052057

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 26 Nov 2020 09:37:10
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User entered empty.	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:32:38

FDA-CBER-2022-1614-6052058

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 26 Nov 2020 09:37:10
Frequency

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User entered 'as needed (PRN)'	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:32:38

FDA-CBER-2022-1614-6052059

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 26 Nov 2020 09:37:10
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User entered empty.	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:32:38

FDA-CBER-2022-1614-6052060

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 26 Nov 2020 09:37:10
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User entered 'Oral (ORAL)'	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:32:38

FDA-CBER-2022-1614-6052061

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 26 Nov 2020 09:37:10
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User entered empty.	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:32:38

FDA-CBER-2022-1614-6052062

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 26 Nov 2020 09:37:10
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User entered 'UN Aug 2020'	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:32:38

FDA-CBER-2022-1614-6052063

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 26 Nov 2020 09:37:10
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User entered '0'	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:32:38

FDA-CBER-2022-1614-6052064

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 26 Nov 2020 09:37:10
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User entered 'Yes (Y)'	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:32:38

FDA-CBER-2022-1614-6052065

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 26 Nov 2020 09:37:10
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User entered empty.	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:32:38

FDA-CBER-2022-1614-6052066

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 26 Nov 2020 09:37:10
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User entered 'No (N)'	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:32:38

FDA-CBER-2022-1614-6052067

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 26 Nov 2020 09:37:10
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 17:32:38

FDA-CBER-2022-1614-6052068

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 26 Nov 2020 09:37:10
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 17:32:38

FDA-CBER-2022-1614-6052069

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 26 Nov 2020 09:37:10
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 17:32:38

FDA-CBER-2022-1614-6052070

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 26 Nov 2020 09:37:10
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: MOTRIN [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 17:35:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 17:35:46
Data point term sent to Coder	System	13 Nov 2020 17:35:03
User entered 'Motrin'	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:34:38

FDA-CBER-2022-1614-6052071

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 26 Nov 2020 09:37:10
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User entered 'No (N)'	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:34:38

FDA-CBER-2022-1614-6052072

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 26 Nov 2020 09:37:10
Indication

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User entered 'Neck pain'	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:34:38

FDA-CBER-2022-1614-6052073

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 26 Nov 2020 09:37:10
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4)	20 Nov 2020 04:15:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 17:07:02
User entered '800'	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:34:38

FDA-CBER-2022-1614-6052074

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 26 Nov 2020 09:37:10
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User entered 'mg (mg)'	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:34:38

FDA-CBER-2022-1614-6052075

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 26 Nov 2020 09:37:10
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User entered empty.	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:34:38

FDA-CBER-2022-1614-6052076

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 26 Nov 2020 09:37:10
Frequency

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User entered 'twice daily (BID)'	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:34:38

FDA-CBER-2022-1614-6052077

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 26 Nov 2020 09:37:10
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User entered empty.	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:34:38

FDA-CBER-2022-1614-6052078

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 26 Nov 2020 09:37:10
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User entered 'Oral (ORAL)'	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:34:38

FDA-CBER-2022-1614-6052079

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 26 Nov 2020 09:37:10
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User entered empty.	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:34:38

FDA-CBER-2022-1614-6052080

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 26 Nov 2020 09:37:10
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User entered '10 Nov 2020'	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:34:38

FDA-CBER-2022-1614-6052081

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 26 Nov 2020 09:37:10
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User entered '0'	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:34:38

FDA-CBER-2022-1614-6052082

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 26 Nov 2020 09:37:10
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User entered 'Yes (Y)'	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:34:38

FDA-CBER-2022-1614-6052083

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 26 Nov 2020 09:37:10
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User entered empty.	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:34:38

FDA-CBER-2022-1614-6052084

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 26 Nov 2020 09:37:10
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User entered 'No (N)'	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:34:38

FDA-CBER-2022-1614-6052085

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 26 Nov 2020 09:37:10
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '2'	System	13 Nov 2020 17:34:38

FDA-CBER-2022-1614-6052086

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 26 Nov 2020 09:37:10
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	13 Nov 2020 17:34:38

FDA-CBER-2022-1614-6052087

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 26 Nov 2020 09:37:10
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Nov 2020 17:34:38

FDA-CBER-2022-1614-6052088

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 26 Nov 2020 09:37:10
Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: SALICYLIC ACID AND DERIVATIVES, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Nov 2020 01:30:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Nov 2020 01:30:16
Data point term sent to Coder	System	24 Nov 2020 18:53:16
User closed query 'CDM-Coding: Please update the eCRF to include the active ingredient name(s) in brackets next to the drug.' (Site from System).	System	24 Nov 2020 18:52:27
Query 'CDM-Coding: Please update the eCRF to include the active ingredient name(s) in brackets next to the drug.' answered with 'this was already done (ASPIRIN)' (Site from System).	Elissa Malkin (b) (4) (b) (4)	24 Nov 2020 18:52:27
User opened query 'CDM-Coding: Please update the eCRF to include the active ingredient name(s) in brackets next to the drug.' (Site from System).	Coder Import (b) (4) (b) (4)	23 Nov 2020 09:36:08
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
Data point term sent to Coder	System	13 Nov 2020 17:36:06
User entered 'BC Powder (aspirin)'	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:35:26

FDA-CBER-2022-1614-6052089

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 26 Nov 2020 09:37:10
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User entered 'No (N)'	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:35:26

FDA-CBER-2022-1614-6052090

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 26 Nov 2020 09:37:10
Indication

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User entered 'Headache'	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:35:26

FDA-CBER-2022-1614-6052091

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 26 Nov 2020 09:37:10
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User entered '1'	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:35:26

FDA-CBER-2022-1614-6052092

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 26 Nov 2020 09:37:10
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User entered 'Other (OTHER)'	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:35:26

FDA-CBER-2022-1614-6052093

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 26 Nov 2020 09:37:10
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User entered 'packet'	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:35:26

FDA-CBER-2022-1614-6052094

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 26 Nov 2020 09:37:10
Frequency

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User entered 'twice daily (BID)'	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:35:26

FDA-CBER-2022-1614-6052095

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 26 Nov 2020 09:37:10
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User entered empty.	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:35:26

FDA-CBER-2022-1614-6052096

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 26 Nov 2020 09:37:10
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User entered 'Oral (ORAL)'	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:35:26

FDA-CBER-2022-1614-6052097

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 26 Nov 2020 09:37:10
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User entered empty.	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:35:26

FDA-CBER-2022-1614-6052098

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 26 Nov 2020 09:37:10
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User entered '23 Oct 2020'	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:35:26

FDA-CBER-2022-1614-6052099

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 26 Nov 2020 09:37:10
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User entered '0'	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:35:26

FDA-CBER-2022-1614-6052100

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 26 Nov 2020 09:37:10
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User entered 'No (N)'	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:35:26

FDA-CBER-2022-1614-6052101

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 26 Nov 2020 09:37:10
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User entered '25 Oct 2020'	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:35:26

FDA-CBER-2022-1614-6052102

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 26 Nov 2020 09:37:10
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	20 Nov 2020 04:15:40
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 17:07:02
User entered 'No (N)'	Erika Faust (b) (4) (b) (4)	13 Nov 2020 17:35:26

FDA-CBER-2022-1614-6052103

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 26 Nov 2020 09:37:10
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '2'	System	13 Nov 2020 17:35:26

FDA-CBER-2022-1614-6052104

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 26 Nov 2020 09:37:10
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	13 Nov 2020 17:35:26

FDA-CBER-2022-1614-6052105

US3542168
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 26 Nov 2020 09:37:10
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Nov 2020 17:35:26

FDA-CBER-2022-1614-6052106

US3542168
Folder: End of Study (1)
Form: Dosing Discontinuation
Generated On: 26 Nov 2020 09:37:10
Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Oct 2020 18:46:00
User entered '08 Oct 2020'	Hannah Yellin (b) (4) (b) (4)	19 Oct 2020 19:32:56

FDA-CBER-2022-1614-6052107

US3542168
Folder: End of Study (1)
Form: Dosing Discontinuation
Generated On: 26 Nov 2020 09:37:10
Primary reason for dosing discontinuation

Audit	User	Time (GMT)
Query 'Per CDM: reason for discontinuation is recorded as PI decision relating to hospital admissions for psychiatric reason; however there is no adverse event recorded for this other than Exacerbation of Anxiety. Please review and consider updating AE form appropriately with action to IP as IP Withdrawn and update this page accordingly.' answered with 'AE form updated with IP withdrawn. It was the PI decision to discontinue dosing as a result of 2 AEs that occurred close temporally' (Site from DM).	Elissa Malkin (b) (4) (b) (4)	24 Nov 2020 18:32:56
User opened query 'Per CDM: reason for discontinuation is recorded as PI decision relating to hospital admissions for psychiatric reason; however there is no adverse event recorded for this other than Exacerbation of Anxiety. Please review and consider updating AE form appropriately with action to IP as IP Withdrawn and update this page accordingly.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 16:12:52
Query 'Per CDM: reason for discontinuation is recorded as PI decision relating to hospital admissions for psychiatric reason; however there si no adverse event recorded for this other than Exacerbation of Anxiety. Please review and consider updating AE form appropriately with action to IP as IP Withdrawn and update this page accordingly.' canceled (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 16:12:39
User opened query 'Per CDM: reason for discontinuation is recorded as PI decision relating to hospital admissions for psychiatric reason; however there si no adverse event recorded for this other than Exacerbation of Anxiety. Please review and consider updating AE form appropriately with action to IP as IP Withdrawn and update this page accordingly.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 16:11:54
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Oct 2020 18:46:00
User entered 'Physician decision (specify) (PHYSICIAN DECISION)'	Hannah Yellin (b) (4) (b) (4)	19 Oct 2020 19:32:56

FDA-CBER-2022-1614-6052108

US3542168
Folder: End of Study (1)
Form: Dosing Discontinuation
Generated On: 26 Nov 2020 09:37:10
If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
User signature succeeded.	David Diemert (b) (4) (b) (4)	21 Oct 2020 18:46:00
User entered 'Physician withheld dose due to hospital admissions for psychiatric reasons'	Hannah Yellin (b) (4) (b) (4)	19 Oct 2020 19:32:56

FDA-CBER-2022-1614-6052109

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 09:37:10
SAEID

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'USA-US084-2020-MRNA-1273-P301000001'	System	20 Sep 2020 17:52:47

FDA-CBER-2022-1614-6052110

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 09:37:10
Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'Yes (Y)'	System	20 Sep 2020 17:52:47

FDA-CBER-2022-1614-6052111

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 09:37:10
Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'No (N)'	System	20 Sep 2020 17:52:47

FDA-CBER-2022-1614-6052112

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 09:37:10
Life threatening

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'No (N)'	System	20 Sep 2020 17:52:47

FDA-CBER-2022-1614-6052113

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 09:37:10
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'Yes (Y)'	System	20 Sep 2020 17:52:47

FDA-CBER-2022-1614-6052114

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 09:37:10
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'No (N)'	System	20 Sep 2020 17:52:47

FDA-CBER-2022-1614-6052115

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 09:37:10
Congenital anomaly or birth defect

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'No (N)'	System	20 Sep 2020 17:52:47

FDA-CBER-2022-1614-6052116

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 09:37:10
Other medically important event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'No (N)'	System	20 Sep 2020 17:52:47

FDA-CBER-2022-1614-6052117

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 09:37:10
Investigator's First Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'David'	System	20 Sep 2020 17:52:47

FDA-CBER-2022-1614-6052118

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 09:37:10
Investigator's Last Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'Diemert'	System	20 Sep 2020 17:52:47

FDA-CBER-2022-1614-6052119

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 09:37:10
Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered '2300 Eye Street NW'	System	20 Sep 2020 17:52:47

FDA-CBER-2022-1614-6052120

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 09:37:10
Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'Washington'	System	20 Sep 2020 17:52:47

FDA-CBER-2022-1614-6052121

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 09:37:10
Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'DC'	System	20 Sep 2020 17:52:47

FDA-CBER-2022-1614-6052122

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 09:37:10
Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered '20037'	System	20 Sep 2020 17:52:47

FDA-CBER-2022-1614-6052123

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 09:37:10
Investigator Country

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:00:57
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered 'US'	System (b) (4)	20 Sep 2020 17:53:12

FDA-CBER-2022-1614-6052124

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 09:37:10
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Signature has been broken.	System	23 Nov 2020 14:38:41
User entered '5'	System	23 Nov 2020 14:38:41
User signature succeeded.	David Diemert (b) (4) (b) (4)	30 Oct 2020 01:28:16
Signature has been broken.	System	28 Oct 2020 18:06:27
User entered '4'	System	28 Oct 2020 18:06:27
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
Signature has been broken.	System	30 Sep 2020 17:33:06
User entered '3'	System	30 Sep 2020 17:33:06
User signature succeeded.	David Diemert (b) (4) (b) (4)	29 Sep 2020 04:31:49
Signature has been broken.	System	28 Sep 2020 14:01:09
User entered '2'	System	28 Sep 2020 14:01:09
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered '1'	System	20 Sep 2020 17:53:12

FDA-CBER-2022-1614-6052125

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 09:37:10
SAEID

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'USA-US084-2020-MRNA-1273-P301000001'	System	20 Sep 2020 17:52:47

FDA-CBER-2022-1614-6052126

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 09:37:10
Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'Yes (Y)'	System	20 Sep 2020 17:52:47

FDA-CBER-2022-1614-6052127

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 09:37:10
Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'No (N)'	System	20 Sep 2020 17:52:47

FDA-CBER-2022-1614-6052128

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 09:37:10
Life threatening

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'No (N)'	System	20 Sep 2020 17:52:47

FDA-CBER-2022-1614-6052129

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 09:37:10
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'Yes (Y)'	System	20 Sep 2020 17:52:47

FDA-CBER-2022-1614-6052130

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 09:37:10
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'No (N)'	System	20 Sep 2020 17:52:47

FDA-CBER-2022-1614-6052131

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 09:37:10
Congenital anomaly or birth defect

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'No (N)'	System	20 Sep 2020 17:52:47

FDA-CBER-2022-1614-6052132

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 09:37:10
Other medically important event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'No (N)'	System	20 Sep 2020 17:52:47

FDA-CBER-2022-1614-6052133

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 09:37:10
Investigator's First Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'David'	System	20 Sep 2020 17:52:47

FDA-CBER-2022-1614-6052134

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 09:37:10
Investigator's Last Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'Diemert'	System	20 Sep 2020 17:52:47

FDA-CBER-2022-1614-6052135

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 09:37:10
Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered '2300 Eye Street NW'	System	20 Sep 2020 17:52:47

FDA-CBER-2022-1614-6052136

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 09:37:10
Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'Washington'	System	20 Sep 2020 17:52:47

FDA-CBER-2022-1614-6052137

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 09:37:10
Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'DC'	System	20 Sep 2020 17:52:47

FDA-CBER-2022-1614-6052138

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 09:37:10
Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered '20037'	System	20 Sep 2020 17:52:47

FDA-CBER-2022-1614-6052139

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 09:37:10
Investigator Country

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:00:57
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered 'US'	System	20 Sep 2020 17:53:12

FDA-CBER-2022-1614-6052140

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 09:37:10
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Signature has been broken.	System	23 Nov 2020 14:38:41
User entered '5'	System	23 Nov 2020 14:38:41
User signature succeeded.	David Diemert (b) (4) (b) (4)	30 Oct 2020 01:28:16
Signature has been broken.	System	28 Oct 2020 18:06:27
User entered '4'	System	28 Oct 2020 18:06:27
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
Signature has been broken.	System	30 Sep 2020 17:33:06
User entered '3'	System	30 Sep 2020 17:33:06
User signature succeeded.	David Diemert (b) (4) (b) (4)	29 Sep 2020 04:31:49
Signature has been broken.	System	28 Sep 2020 14:01:09
User entered '2'	System	28 Sep 2020 14:01:09
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered '1'	System	20 Sep 2020 17:53:12

FDA-CBER-2022-1614-6052141

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form (1)
Generated On: 26 Nov 2020 09:37:10
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered '20/Sep/2020 13:53'	(b) (4) System	20 Sep 2020 17:53:12

FDA-CBER-2022-1614-6052142

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:37:10

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:00:57
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered '1'	(b) (4), (b) (6)	20 Sep 2020 17:53:12

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 09:37:10
SAEID

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'USA-US084-2020-MRNA-1273-P301000001'	System	20 Sep 2020 17:52:47

FDA-CBER-2022-1614-6052144

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 09:37:10
Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'Yes (Y)'	System	20 Sep 2020 17:52:47

FDA-CBER-2022-1614-6052145

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 09:37:10
Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'No (N)'	System	20 Sep 2020 17:52:47

FDA-CBER-2022-1614-6052146

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 09:37:10
Life threatening

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'No (N)'	System	20 Sep 2020 17:52:47

FDA-CBER-2022-1614-6052147

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 09:37:10
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'Yes (Y)'	System	20 Sep 2020 17:52:47

FDA-CBER-2022-1614-6052148

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 09:37:10
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'No (N)'	System	20 Sep 2020 17:52:47

FDA-CBER-2022-1614-6052149

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 09:37:10
Congenital anomaly or birth defect

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'No (N)'	System	20 Sep 2020 17:52:47

FDA-CBER-2022-1614-6052150

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 09:37:10
Other medically important event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'No (N)'	System	20 Sep 2020 17:52:47

FDA-CBER-2022-1614-6052151

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 09:37:10
Investigator's First Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'David'	System	20 Sep 2020 17:52:47

FDA-CBER-2022-1614-6052152

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 09:37:10
Investigator's Last Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'Diemert'	System	20 Sep 2020 17:52:47

FDA-CBER-2022-1614-6052153

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 09:37:10
Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered '2300 Eye Street NW'	System	20 Sep 2020 17:52:47

FDA-CBER-2022-1614-6052154

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 09:37:10
Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'Washington'	System	20 Sep 2020 17:52:47

FDA-CBER-2022-1614-6052155

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 09:37:10
Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'DC'	System	20 Sep 2020 17:52:47

FDA-CBER-2022-1614-6052156

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 09:37:10
Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered '20037'	System	20 Sep 2020 17:52:47

FDA-CBER-2022-1614-6052157

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 09:37:10
Investigator Country

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:00:57
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered 'US'	System	20 Sep 2020 17:53:12

FDA-CBER-2022-1614-6052158

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 09:37:10
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Signature has been broken.	System	23 Nov 2020 14:38:41
User entered '5'	System	23 Nov 2020 14:38:41
User signature succeeded.	David Diemert (b) (4) (b) (4)	30 Oct 2020 01:28:16
Signature has been broken.	System	28 Oct 2020 18:06:27
User entered '4'	System	28 Oct 2020 18:06:27
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
Signature has been broken.	System	30 Sep 2020 17:33:06
User entered '3'	System	30 Sep 2020 17:33:06
User signature succeeded.	David Diemert (b) (4) (b) (4)	29 Sep 2020 04:31:49
Signature has been broken.	System	28 Sep 2020 14:01:09
User entered '2'	System	28 Sep 2020 14:01:09
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered '1'	System	20 Sep 2020 17:53:12

FDA-CBER-2022-1614-6052159

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form (2)
Generated On: 26 Nov 2020 09:37:10
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	29 Sep 2020 04:31:49
User entered '28/Sep/2020 10:01'	System (b) (4)	28 Sep 2020 14:01:09

FDA-CBER-2022-1614-6052160

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:37:10

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 17:32:52
User signature succeeded.	David Diemert (b) (4) (b) (4)	29 Sep 2020 04:31:49
User entered '1'	(b) (4), (b) (6)	28 Sep 2020 14:01:09

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 09:37:10
SAEID

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'USA-US084-2020-MRNA-1273-P301000001'	System	20 Sep 2020 17:52:47

FDA-CBER-2022-1614-6052162

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 09:37:10
Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'Yes (Y)'	System	20 Sep 2020 17:52:47

FDA-CBER-2022-1614-6052163

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 09:37:10
Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'No (N)'	System	20 Sep 2020 17:52:47

FDA-CBER-2022-1614-6052164

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 09:37:10
Life threatening

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'No (N)'	System	20 Sep 2020 17:52:47

FDA-CBER-2022-1614-6052165

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 09:37:10
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'Yes (Y)'	System	20 Sep 2020 17:52:47

FDA-CBER-2022-1614-6052166

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 09:37:10
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'No (N)'	System	20 Sep 2020 17:52:47

FDA-CBER-2022-1614-6052167

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 09:37:10
Congenital anomaly or birth defect

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'No (N)'	System	20 Sep 2020 17:52:47

FDA-CBER-2022-1614-6052168

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 09:37:10
Other medically important event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'No (N)'	System	20 Sep 2020 17:52:47

FDA-CBER-2022-1614-6052169

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 09:37:10
Investigator's First Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'David'	System	20 Sep 2020 17:52:47

FDA-CBER-2022-1614-6052170

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 09:37:10
Investigator's Last Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'Diemert'	System	20 Sep 2020 17:52:47

FDA-CBER-2022-1614-6052171

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 09:37:10
Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered '2300 Eye Street NW'	System	20 Sep 2020 17:52:47

FDA-CBER-2022-1614-6052172

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 09:37:10
Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'Washington'	System	20 Sep 2020 17:52:47

FDA-CBER-2022-1614-6052173

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 09:37:10
Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'DC'	System	20 Sep 2020 17:52:47

FDA-CBER-2022-1614-6052174

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 09:37:10
Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered '20037'	System	20 Sep 2020 17:52:47

FDA-CBER-2022-1614-6052175

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 09:37:10
Investigator Country

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:00:57
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered 'US'	(b) (4) System	20 Sep 2020 17:53:12

FDA-CBER-2022-1614-6052176

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 09:37:10
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Signature has been broken.	System	23 Nov 2020 14:38:41
User entered '5'	System	23 Nov 2020 14:38:41
User signature succeeded.	David Diemert (b) (4) (b) (4)	30 Oct 2020 01:28:16
Signature has been broken.	System	28 Oct 2020 18:06:27
User entered '4'	System	28 Oct 2020 18:06:27
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
Signature has been broken.	System	30 Sep 2020 17:33:06
User entered '3'	System	30 Sep 2020 17:33:06
User signature succeeded.	David Diemert (b) (4) (b) (4)	29 Sep 2020 04:31:49
Signature has been broken.	System	28 Sep 2020 14:01:09
User entered '2'	System	28 Sep 2020 14:01:09
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered '1'	System	20 Sep 2020 17:53:12

FDA-CBER-2022-1614-6052177

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form (3)
Generated On: 26 Nov 2020 09:37:10
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered '30/Sep/2020 17:33'	(b) (4) System	30 Sep 2020 17:33:06

FDA-CBER-2022-1614-6052178

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:37:10

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 18:06:16
User signature succeeded.	David Diemert (b) (4)	01 Oct 2020 04:09:18
User entered '1'	(b) (4), (b) (6)	30 Sep 2020 17:33:06

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 09:37:10
SAEID

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'USA-US084-2020-MRNA-1273-P301000001'	System	20 Sep 2020 17:52:47

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 09:37:10
Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'Yes (Y)'	System	20 Sep 2020 17:52:47

FDA-CBER-2022-1614-6052181

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 09:37:10
Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'No (N)'	System	20 Sep 2020 17:52:47

FDA-CBER-2022-1614-6052182

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 09:37:10
Life threatening

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'No (N)'	System	20 Sep 2020 17:52:47

FDA-CBER-2022-1614-6052183

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 09:37:10
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'Yes (Y)'	System	20 Sep 2020 17:52:47

FDA-CBER-2022-1614-6052184

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 09:37:10
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'No (N)'	System	20 Sep 2020 17:52:47

FDA-CBER-2022-1614-6052185

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 09:37:10
Congenital anomaly or birth defect

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'No (N)'	System	20 Sep 2020 17:52:47

FDA-CBER-2022-1614-6052186

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 09:37:10
Other medically important event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'No (N)'	System	20 Sep 2020 17:52:47

FDA-CBER-2022-1614-6052187

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 09:37:10
Investigator's First Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'David'	System	20 Sep 2020 17:52:47

FDA-CBER-2022-1614-6052188

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 09:37:10
Investigator's Last Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'Diemert'	System	20 Sep 2020 17:52:47

FDA-CBER-2022-1614-6052189

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 09:37:10
Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered '2300 Eye Street NW'	System	20 Sep 2020 17:52:47

FDA-CBER-2022-1614-6052190

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 09:37:10
Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'Washington'	System	20 Sep 2020 17:52:47

FDA-CBER-2022-1614-6052191

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 09:37:10
Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'DC'	System	20 Sep 2020 17:52:47

FDA-CBER-2022-1614-6052192

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 09:37:10
Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered '20037'	System	20 Sep 2020 17:52:47

FDA-CBER-2022-1614-6052193

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 09:37:10
Investigator Country

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:00:57
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
User entered 'US'	(b) (4) System	20 Sep 2020 17:53:12

FDA-CBER-2022-1614-6052194

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 09:37:10
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Signature has been broken.	System	23 Nov 2020 14:38:41
User entered '5'	System	23 Nov 2020 14:38:41
User signature succeeded.	David Diemert (b) (4) (b) (4)	30 Oct 2020 01:28:16
Signature has been broken.	System	28 Oct 2020 18:06:27
User entered '4'	System	28 Oct 2020 18:06:27
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
Signature has been broken.	System	30 Sep 2020 17:33:06
User entered '3'	System	30 Sep 2020 17:33:06
User signature succeeded.	David Diemert (b) (4) (b) (4)	29 Sep 2020 04:31:49
Signature has been broken.	System	28 Sep 2020 14:01:09
User entered '2'	System	28 Sep 2020 14:01:09
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered '1'	System	20 Sep 2020 17:53:12

FDA-CBER-2022-1614-6052195

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form (4)
Generated On: 26 Nov 2020 09:37:10
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 01:28:16
User entered '28/Oct/2020 14:06'	System (b) (4)	28 Oct 2020 18:06:27

FDA-CBER-2022-1614-6052196

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 09:37:10

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 14:38:28
User signature succeeded.	David Diemert (b) (4)	30 Oct 2020 01:28:16
User entered '1'	(b) (4), (b) (6)	28 Oct 2020 18:06:27

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 09:37:10
SAEID

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'USA-US084-2020-MRNA-1273-P301000001'	System	20 Sep 2020 17:52:47

FDA-CBER-2022-1614-6052198

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 09:37:10
Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'Yes (Y)'	System	20 Sep 2020 17:52:47

FDA-CBER-2022-1614-6052199

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 09:37:10
Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'No (N)'	System	20 Sep 2020 17:52:47

FDA-CBER-2022-1614-6052200

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 09:37:10
Life threatening

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'No (N)'	System	20 Sep 2020 17:52:47

FDA-CBER-2022-1614-6052201

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 09:37:10
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'Yes (Y)'	System	20 Sep 2020 17:52:47

FDA-CBER-2022-1614-6052202

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 09:37:10
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'No (N)'	System	20 Sep 2020 17:52:47

FDA-CBER-2022-1614-6052203

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 09:37:10
Congenital anomaly or birth defect

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'No (N)'	System	20 Sep 2020 17:52:47

FDA-CBER-2022-1614-6052204

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 09:37:10
Other medically important event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'No (N)'	System	20 Sep 2020 17:52:47

FDA-CBER-2022-1614-6052205

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 09:37:10
Investigator's First Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'David'	System	20 Sep 2020 17:52:47

FDA-CBER-2022-1614-6052206

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 09:37:10
Investigator's Last Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'Diemert'	System	20 Sep 2020 17:52:47

FDA-CBER-2022-1614-6052207

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 09:37:10
Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered '2300 Eye Street NW'	System	20 Sep 2020 17:52:47

FDA-CBER-2022-1614-6052208

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 09:37:10
Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'Washington'	System	20 Sep 2020 17:52:47

FDA-CBER-2022-1614-6052209

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 09:37:10
Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered 'DC'	System	20 Sep 2020 17:52:47

FDA-CBER-2022-1614-6052210

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 09:37:10
Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User signature succeeded.	David Diemert (b) (4)	24 Sep 2020 11:50:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Sep 2020 17:53:07
User entered '20037'	System	20 Sep 2020 17:52:47

FDA-CBER-2022-1614-6052211

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 09:37:10
Investigator Country

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
Reviewed for Safety.	(b) (4), (b) (6)	28 Sep 2020 14:00:57
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered 'US'	System	20 Sep 2020 17:53:12

FDA-CBER-2022-1614-6052212

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form
Generated On: 26 Nov 2020 09:37:10
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Signature has been broken.	System	23 Nov 2020 14:38:41
User entered '5'	System	23 Nov 2020 14:38:41
User signature succeeded.	David Diemert (b) (4) (b) (4)	30 Oct 2020 01:28:16
Signature has been broken.	System	28 Oct 2020 18:06:27
User entered '4'	System	28 Oct 2020 18:06:27
User signature succeeded.	David Diemert (b) (4) (b) (4)	01 Oct 2020 04:09:18
Signature has been broken.	System	30 Sep 2020 17:33:06
User entered '3'	System	30 Sep 2020 17:33:06
User signature succeeded.	David Diemert (b) (4) (b) (4)	29 Sep 2020 04:31:49
Signature has been broken.	System	28 Sep 2020 14:01:09
User entered '2'	System	28 Sep 2020 14:01:09
User signature succeeded.	David Diemert (b) (4) (b) (4)	24 Sep 2020 11:50:07
User entered '1'	System	20 Sep 2020 17:53:12

FDA-CBER-2022-1614-6052213

US3542168
Folder: SAE USA-US084-2020-MRNA-1273-P301000001
Form: Safety Report Form (5)
Generated On: 26 Nov 2020 09:37:10
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User entered '23/Nov/2020 09:38'	System	23 Nov 2020 14:38:41

FDA-CBER-2022-1614-6052214

US3542168

Folder: SAE USA-US084-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 26 Nov 2020 09:37:10

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:21:28
User entered '1'	(b) (4), (b) (6)	23 Nov 2020 14:38:41