US3672163 (Prod: Coastal Carolina Research Center)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:21:33

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US3672163
Form: Participant Creation
Data signed: (b) (4) **05 Mar 2021 17:57:42**
Generated On: 10 Jun 2021 09:21:33

Participant ID	US3672163

mRNA-1273-P301 Completion Guidelines

FDA-CBER-2022-1614-2936519

US3672163
Folder: Screening
Form: Visit Date
Data signed: (b) (4) **15 Feb 2021 19:59:54**
Generated On: 10 Jun 2021 09:21:33

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	18 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	SCRN

FDA-CBER-2022-1614-2936520

US3672163
Folder: Screening
Form: Demographics
Data signed: (b) (4) **15 Feb 2021 19:59:53**
Generated On: 10 Jun 2021 09:21:33

Date of Birth (MMM yyyy)	(b) (6) 1964
Age	56
Age Units	YEARS
Age (Derived)	56
Sex	Female ■ Male ☐
Ethnicity	Hispanic or Latino ☐ Not Hispanic or Latino ■ Not Reported ☐ Unknown ☐
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify	
Unknown	False
Not reported	False

FDA-CBER-2022-1614-2936521

US3672163
Folder: Screening
Form: Enrollment
Data signed: (b) (4) **15 Feb 2021 19:59:53**
Generated On: 10 Jun 2021 09:21:33

Date of Informed Consent *(dd MMM yyyy)*	18 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 ☐ Amendment 2 ■ Amendment 3 ☐ Amendment 4 ☐ Amendment 5 ☐
Was participant enrolled in the study?	Yes ■ No ☐
If No, indicate reason for screen fail	Withdrew Consent ☐ Inclusion/Exclusion ☐ Cohort Full ☐ Other ☐
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes ☐ No ■
If Yes, previous participant number	
Enrollment Trigger	1

FDA-CBER-2022-1614-2936522

US3672163
Folder: Screening
Form: Inclusion/Exclusion Criteria Summary
Data signed: (b) (4) **15 Feb 2021 19:59:53**
Generated On: 10 Jun 2021 09:21:33

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

US3672163
Folder: Screening
Form: Medical History Summary
Data signed: (b) (4) **15 Feb 2021 19:59:53**
Generated On: 10 Jun 2021 09:21:33

Were any significant conditions reported?	Yes ■ No ☐

FDA-CBER-2022-1614-2936524

US3672163
Folder: Screening
Form: Medical History (1)
Data signed: (b) (4) **15 Feb 2021 19:59:53**
Generated On: 10 Jun 2021 09:21:33

Condition	CHOLECYSTECTOMY DUE TO GALLSTONES
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)	UN UNK 2018
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	JAN 2018
Stop Year (derived)	2018

FDA-CBER-2022-1614-2936525

US3672163
Folder: Screening
Form: Medical History (2)
Data signed: (b) (4) **15 Feb 2021 19:59:53**
Generated On: 10 Jun 2021 09:21:33

Condition	VASOMOTOR SYMPTOMS
Start date (dd MMM yyyy)	UN UNK 2017
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 2017
Start Year (derived)	2017
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-2936526

US3672163
Folder: Screening
Form: Medical History (3)
Data signed: (b) (4) **15 Feb 2021 19:59:53**
Generated On: 10 Jun 2021 09:21:33

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

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US3672163
Folder: Screening
Form: Medical History (4)
Data signed: (b) (4) **15 Feb 2021 19:59:53**
Generated On: 10 Jun 2021 09:21:33

Condition	INTERMITTENT POST CHOLECYSTECTOMY DIARRHEA
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-2022-1614-2936528

US3672163
Folder: Screening
Form: Medical History (5)
Data signed: (b) (4) **15 Feb 2021 19:59:53**
Generated On: 10 Jun 2021 09:21:33

Condition	POST MENOPAUSAL
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes ●
	No ○
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-2936529

US3672163
Folder: Screening
Form: Vital Signs
Data signed: (b) (4) **15 Feb 2021 19:59:54**
Generated On: 10 Jun 2021 09:21:33

Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	18 AUG 2020
Time of assessment *(00:00-23:59)*	13:08 (24 HR)
Vital Signs Date and Time (derived)	18 AUG 2020 13:08
Height *(xxx.x)*	157.6 cm
Weight *(xxx.x)*	91.9 kg
BMI *(xxx.x)*	37.00012 kg/m^2
BMI units	KG/M2
Temperature *(xxx.x)*	ND - Not Done
Route of measurement	Oral ☐ Axillary ☐ Other ■
If Other, specify	ND - Not Done
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-2022-1614-2936530

US3672163
Folder: Screening
Form: Physical Examination
Data signed: (b) (4) **15 Feb 2021 19:59:53**
Generated On: 10 Jun 2021 09:21:33

Was the physical examination performed?	Yes ☑ No ☐
Date of examination *(dd MMM yyyy)*	18 AUG 2020

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

FDA-CBER-2022-1614-2936531

US3672163
Folder: Screening
Form: Childbearing Potential
Data signed: (b) (4) **15 Feb 2021 19:59:53**
Generated On: 10 Jun 2021 09:21:33

Date of assessment *(dd MMM yyyy)*	18 AUG 2020
Is the participant of childbearing potential?	Yes ☐ No ■
If No, what is the reason?	Surgically sterile ☐ Post-menopausal ■ Partner medically sterile ☐ Not reached age of Menarche ☐ Other ☐
If Partner medically sterile or Other, specify	
If Surgically sterile, date of surgery *(dd MMM yyyy)*	
Date of surgery unknown	False
If Post-menopausal, date of last menstruation *(dd MMM yyyy)*	UN UNK 2015
Date of last menstruation unknown	False

FDA-CBER-2022-1614-2936532

US3672163
Folder: Screening
Form: Risk of Exposure
Data signed: (b) (4) **15 Feb 2021 19:59:53**
Generated On: 10 Jun 2021 09:21:33

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	(b) (6) VOLUNTEER.
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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US3672163
Folder: Screening
Form: Risk of Exposure
Data signed: (b) (4) **15 Feb 2021 19:59:53**
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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	True
Specify	RESIDENT IN A COMMUNITY WITH ONGOING PERSON TO PERSON TRANSMISSION.

FDA-CBER-2022-1614-2936534

US3672163
Folder: Visit 1 Day 1
Form: Visit Date
Data signed: (b) (4) **15 Feb 2021 19:59:54**
Generated On: 10 Jun 2021 09:21:33

Was this visit performed?	Yes ☑ No ☐
Visit date (dd MMM yyyy)	18 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ☑
Folder OID	VISIT1

FDA-CBER-2022-1614-2936535

US3672163
Folder: Visit 1 Day 1
Form: Randomization
Data signed: (b) (4) **15 Feb 2021 19:59:54**
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What was the date of randomization? *(dd MMM yyyy)*	18 AUG 2020
What was the participant's randomization number?	105575
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 ■

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US3672163
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Data signed: (b) (4) **15 Feb 2021 19:59:56**
Generated On: 10 Jun 2021 09:21:33

Height	ND - Not Done
Weight	ND - Not Done

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US3672163
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Data signed: (b) (4) **15 Feb 2021 19:59:56**
Generated On: 10 Jun 2021 09:21:33

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)*	18 AUG 2020
Time of assessment *(00:00-23:59)*	13:08 (24 HR)
Vital Signs Date and Time (derived)	18 AUG 2020 13:08
Temperature *(xxx.x)*	99.0 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	61 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	84 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-2936538

US3672163
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Data signed: (b) (4) **15 Feb 2021 19:59:56**
Generated On: 10 Jun 2021 09:21:33

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)*	18 AUG 2020
Time of assessment *(00:00-23:59)*	14:23 (24 HR)
Vital Signs Date and Time (derived)	18 AUG 2020 14:23
Temperature *(xxx.x)*	98.5 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	56 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	76 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-2936539

US3672163
Folder: Visit 1 Day 1
Form: Physical Examination
Data signed: (b) (4) **15 Feb 2021 19:59:54**
Generated On: 10 Jun 2021 09:21:33

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-2022-1614-2936540

US3672163
Folder: Visit 1 Day 1
Form: Exposure
Data signed: (b) (4) **15 Feb 2021 19:59:54**
Generated On: 10 Jun 2021 09:21:33

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)*	18 AUG 2020
What was the treatment time? *(00:00-23:59)*	13:47 (24 HR)
Treatment Date and Time (derived)	18 AUG 2020 13:47
Which arm was used to give treatment?	Left Arm ☐ Right Arm ■
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

FDA-CBER-2022-1614-2936541

US3672163
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Data signed: (b) (4) **15 Feb 2021 19:59:54**
Generated On: 10 Jun 2021 09:21:33

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	18 AUG 2020
Collection time *(00:00-23:59)*	13:22 (24 HR)
Collection date and time (derived)	18 AUG 2020 13:22

FDA-CBER-2022-1614-2936542

Collection date *(dd MMM yyyy)* 18 AUG 2020

Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:54	18 AUG 2020 12:54
Nasopharyngeal Swab 2	No		

US3672163
Folder: Visit 1 Day 1
Form: Continuing
Data signed: (b) (4) **15 Feb 2021 19:59:54**
Generated On: 10 Jun 2021 09:21:33

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

FDA-CBER-2022-1614-2936544

US3672163
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:21:33

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**	98.5 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	18 AUG 2020 14:20
PC Open Date & Time	18 AUG 2020 14:07
PC Close Date & Time	18 AUG 2020 16:37

FDA-CBER-2022-1614-2936545

US3672163
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:21:33

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	97.9 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	18 AUG 2020 17:34
PC Open Date & Time	18 AUG 2020 17:32
PC Close Date & Time	19 AUG 2020 11:59

FDA-CBER-2022-1614-2936546

US3672163
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:21:33

TIMEPOINT	DAY 2

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	98.6 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	19 AUG 2020 22:33
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3672163
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:21:33

TIMEPOINT	DAY 3

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	98.0 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	20 AUG 2020 17:53
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

FDA-CBER-2022-1614-2936548

US3672163
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:21:33

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**	98.0 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	21 AUG 2020 18:09
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

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US3672163
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:21:33

TIMEPOINT	DAY 5

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	96.5 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	22 AUG 2020 17:43
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3672163
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:21:33

TIMEPOINT	DAY 6

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	97.4 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	24 AUG 2020 08:27
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

FDA-CBER-2022-1614-2936551

US3672163
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:21:33

TIMEPOINT	DAY 7

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	97.6 °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	24 AUG 2020 18:35
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

FDA-CBER-2022-1614-2936552

US3672163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:21:33

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	18 AUG 2020 14:21
PC Open Date & Time	18 AUG 2020 14:07
PC Close Date & Time	18 AUG 2020 16:37

FDA-CBER-2022-1614-2936553

US3672163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:21:33

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	18 AUG 2020 17:35
PC Open Date & Time	18 AUG 2020 17:32
PC Close Date & Time	19 AUG 2020 11:59

FDA-CBER-2022-1614-2936554

US3672163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:21:33

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	19 AUG 2020 22:33
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

FDA-CBER-2022-1614-2936555

US3672163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:21:33

TIMEPOINT	DAY 3
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ☐ Does not interfere with activity ■ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ■ No ☐
Please record - **REDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site redness with the ruler provided.	25
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ■ No ☐
Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site swelling/hardness with the ruler provided.	25
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	20 AUG 2020 17:54
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3672163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:21:33

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	21 AUG 2020 18:10
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

FDA-CBER-2022-1614-2936557

US3672163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:21:33

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 - **SWELLING/HARDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site swelling/hardness with the ruler provided.	2
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	22 AUG 2020 17:43
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

FDA-CBER-2022-1614-2936558

US3672163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:21:33

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	24 AUG 2020 08:28
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

FDA-CBER-2022-1614-2936559

US3672163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:21:33

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	24 AUG 2020 18:35
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

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

FDA-CBER-2022-1614-2936561

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:21:33

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	18 AUG 2020 14:22
PC Open Date & Time	18 AUG 2020 14:07
PC Close Date & Time	18 AUG 2020 16:37

FDA-CBER-2022-1614-2936562

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

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:21:33

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	18 AUG 2020 17:36
PC Open Date & Time	18 AUG 2020 17:32
PC Close Date & Time	19 AUG 2020 11:59

FDA-CBER-2022-1614-2936564

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:21:33

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-2022-1614-2936565

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:21:33

	Yes ☐
PC Time stamp	19 AUG 2020 22:33
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:21:33

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-2022-1614-2936567

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:21:33

	Yes ☐
PC Time stamp	20 AUG 2020 17:55
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

FDA-CBER-2022-1614-2936568

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:21:33

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-2022-1614-2936569

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:21:33

	Yes ☐
PC Time stamp	21 AUG 2020 18:10
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

FDA-CBER-2022-1614-2936570

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:21:33

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-2022-1614-2936571

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:21:33

	Yes ☐
PC Time stamp	22 AUG 2020 17:44
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

FDA-CBER-2022-1614-2936572

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:21:33

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-2022-1614-2936573

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:21:33

	Yes ☐
PC Time stamp	24 AUG 2020 08:28
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

FDA-CBER-2022-1614-2936574

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:21:33

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-2022-1614-2936575

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:21:33

	Yes ☐
PC Time stamp	24 AUG 2020 18:35
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3672163
Folder: Safety Call Day 8 (1)
Form: Safety Call
Data signed: (b) (4) **15 Feb 2021 19:59:53**
Generated On: 10 Jun 2021 09:21:33

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	25 AUG 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-2022-1614-2936577

US3672163
Folder: Safety Call Day 8 (1)
Form: Continuing
Data signed: (b) (4) **15 Feb 2021 19:59:53**
Generated On: 10 Jun 2021 09:21:33

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

FDA-CBER-2022-1614-2936578

US3672163
Folder: Safety Call Day 15 (1)
Form: Safety Call
Data signed: (b) (4) **15 Feb 2021 19:59:53**
Generated On: 10 Jun 2021 09:21:33

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	01 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-2022-1614-2936579

US3672163
Folder: Safety Call Day 15 (1)
Form: Continuing
Data signed: (b) (4) **15 Feb 2021 19:59:53**
Generated On: 10 Jun 2021 09:21:33

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

FDA-CBER-2022-1614-2936580

US3672163
Folder: Safety Call Day 22 (1)
Form: Safety Call
Data signed: (b) (4) **15 Feb 2021 19:59:53**
Generated On: 10 Jun 2021 09:21:33

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	09 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-2022-1614-2936581

US3672163
Folder: Safety Call Day 22 (1)
Form: Continuing
Data signed: (b) (4) **15 Feb 2021 19:59:53**
Generated On: 10 Jun 2021 09:21:33

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

FDA-CBER-2022-1614-2936582

US3672163
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Data signed: (b) (4) **15 Feb 2021 19:59:56**
Generated On: 10 Jun 2021 09:21:33

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	14 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	VISIT2

FDA-CBER-2022-1614-2936583

US3672163
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Data signed: (b) (4) **15 Feb 2021 19:59:56**
Generated On: 10 Jun 2021 09:21:33

Timepoint	Pre-Dose ● / Post-Dose ○
Were vital signs assessed?	Yes ● / No ○
Date of assessment *(dd MMM yyyy)*	14 SEP 2020
Time of assessment *(00:00-23:59)*	15:21 (24 HR)
Vital Signs Date and Time (derived)	14 SEP 2020 15:21
Temperature *(xxx.x)*	98.1 F
Route of measurement	Oral ● / Axillary ○ / Other ○
If Other, specify	
Pulse *(xxx)*	68 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	83 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-2936584

US3672163
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Data signed: (b) (4) **15 Feb 2021 19:59:56**
Generated On: 10 Jun 2021 09:21:33

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-2022-1614-2936585

US3672163
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Data signed: (b) (4) **15 Feb 2021 19:59:56**
Generated On: 10 Jun 2021 09:21:33

Was the physical examination performed?	Yes ■ No ☐
Date of examination *(dd MMM yyyy)*	14 SEP 2020

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

FDA-CBER-2022-1614-2936586

US3672163
Folder: Visit 2 Day 29 (1)
Form: Exposure
Data signed: (b) (4) **15 Feb 2021 19:59:56**
Generated On: 10 Jun 2021 09:21:33

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	AE, RIGHT ARM ERYTHEMA AND INDURATION
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-2022-1614-2936587

US3672163
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **15 Feb 2021 19:59:56**
Generated On: 10 Jun 2021 09:21:33

Was the sample collected?	Yes ☑ No ☐
Collection date *(dd MMM yyyy)*	14 SEP 2020
Collection time *(00:00-23:59)*	15:30 (24 HR)
Collection date and time (derived)	14 SEP 2020 15:30

US3672163
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab
Data signed: (b) (4) **15 Feb 2021 19:59:56**
Generated On: 10 Jun 2021 09:21:33

Collection date *(dd MMM yyyy)*			14 SEP 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:41	14 SEP 2020 15:41
Nasopharyngeal Swab 2	No		

FDA-CBER-2022-1614-2936589

US3672163
Folder: Visit 2 Day 29 (1)
Form: Continuing
Data signed: (b) (4) **15 Feb 2021 19:59:56**
Generated On: 10 Jun 2021 09:21:33

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

FDA-CBER-2022-1614-2936590

US3672163
Folder: Safety Call Day 36 (1)
Form: Safety Call
Data signed: (b) (4) **15 Feb 2021 19:59:53**
Generated On: 10 Jun 2021 09:21:33

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

FDA-CBER-2022-1614-2936591

US3672163
Folder: Safety Call Day 36 (1)
Form: Continuing
Data signed: (b) (4) **15 Feb 2021 19:59:53**
Generated On: 10 Jun 2021 09:21:33

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

FDA-CBER-2022-1614-2936592

US3672163
Folder: Safety Call Day 43 (1)
Form: Safety Call
Data signed: (b) (4) **15 Feb 2021 19:59:53**
Generated On: 10 Jun 2021 09:21:33

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	1 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-2022-1614-2936593

US3672163
Folder: Safety Call Day 43 (1)
Form: Continuing
Data signed: (b) (4) **15 Feb 2021 19:59:53**
Generated On: 10 Jun 2021 09:21:33

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

FDA-CBER-2022-1614-2936594

US3672163
Folder: Safety Call Day 50 (1)
Form: Safety Call
Data signed: (b) (4) **15 Feb 2021 19:59:53**
Generated On: 10 Jun 2021 09:21:33

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	5 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-2022-1614-2936595

US3672163
Folder: Safety Call Day 50 (1)
Form: Continuing
Data signed: (b) (4) **15 Feb 2021 19:59:53**
Generated On: 10 Jun 2021 09:21:33

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

FDA-CBER-2022-1614-2936596

US3672163
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Data signed: (b) (4) **15 Feb 2021 19:59:56**
Generated On: 10 Jun 2021 09:21:33

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

FDA-CBER-2022-1614-2936597

US3672163
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Data signed: (b) (4) **15 Feb 2021 19:59:56**
Generated On: 10 Jun 2021 09:21:33

Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	12 OCT 2020
Time of assessment *(00:00-23:59)*	09:05 (24 HR)
Vital Signs Date and Time (derived)	12 OCT 2020 09:05
Temperature *(xxx.x)*	98.5 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	59 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	91 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

FDA-CBER-2022-1614-2936598

US3672163
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Data signed: (b) (4) **15 Feb 2021 19:59:56**
Generated On: 10 Jun 2021 09:21:33

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-2022-1614-2936599

US3672163
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **15 Feb 2021 19:59:56**
Generated On: 10 Jun 2021 09:21:33

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	12 OCT 2020
Collection time *(00:00-23:59)*	09:19 (24 HR)
Collection date and time (derived)	12 OCT 2020 09:19

FDA-CBER-2022-1614-2936600

US3672163
Folder: Visit 3 Day 57 (1)
Form: Continuing
Data signed: (b) (4) **15 Feb 2021 19:59:56**
Generated On: 10 Jun 2021 09:21:33

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

FDA-CBER-2022-1614-2936601

US3672163
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 OCT 2020 19:04:47
Patient Cloud Open Date & Time	18 OCT 2020 00:01
Patient Cloud Close Date & Time	22 OCT 2020 23:59

FDA-CBER-2022-1614-2936602

US3672163
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	25 OCT 2020 08:28:39
Patient Cloud Open Date & Time	25 OCT 2020 00:01
Patient Cloud Close Date & Time	29 OCT 2020 23:59

US3672163
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 NOV 2020 09:39:36
Patient Cloud Open Date & Time	01 NOV 2020 00:01
Patient Cloud Close Date & Time	05 NOV 2020 23:59

US3672163
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33

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 identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	16 NOV 2020 09:08:21
Patient Cloud Open Date & Time	15 NOV 2020 00:01
Patient Cloud Close Date & Time	19 NOV 2020 23:59

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 NOV 2020 07:23:52
Patient Cloud Open Date & Time	19 NOV 2020 00:01
Patient Cloud Close Date & Time	23 NOV 2020 23:59

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	30 NOV 2020 08:30:37
Patient Cloud Open Date & Time	26 NOV 2020 00:01
Patient Cloud Close Date & Time	30 NOV 2020 23:59

FDA-CBER-2022-1614-2936607

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 DEC 2020 19:28:15
Patient Cloud Open Date & Time	03 DEC 2020 00:01
Patient Cloud Close Date & Time	07 DEC 2020 23:59

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 DEC 2020 07:47:46
Patient Cloud Open Date & Time	10 DEC 2020 00:01
Patient Cloud Close Date & Time	14 DEC 2020 23:59

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

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2020 00:01
Patient Cloud Close Date & Time	21 DEC 2020 23:59

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	26 DEC 2020 12:01:13
Patient Cloud Open Date & Time	24 DEC 2020 00:01
Patient Cloud Close Date & Time	28 DEC 2020 23:59

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 JAN 2021 17:30:12
Patient Cloud Open Date & Time	31 DEC 2020 00:01
Patient Cloud Close Date & Time	04 JAN 2021 23:59

FDA-CBER-2022-1614-2936613

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 JAN 2021 07:30:41
Patient Cloud Open Date & Time	07 JAN 2021 00:01
Patient Cloud Close Date & Time	11 JAN 2021 23:59

FDA-CBER-2022-1614-2936614

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ■
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ■
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 JAN 2021 11:08:15
Patient Cloud Open Date & Time	14 JAN 2021 00:01
Patient Cloud Close Date & Time	18 JAN 2021 23:59

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	25 JAN 2021 11:59:33
Patient Cloud Open Date & Time	21 JAN 2021 00:01
Patient Cloud Close Date & Time	25 JAN 2021 23:59

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	30 JAN 2021 12:00:36
Patient Cloud Open Date & Time	28 JAN 2021 00:01
Patient Cloud Close Date & Time	01 FEB 2021 23:59

TIMEPOINT	DAY 173
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

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

FDA-CBER-2022-1614-2936619

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 FEB 2021 12:00:34
Patient Cloud Open Date & Time	11 FEB 2021 00:01
Patient Cloud Close Date & Time	15 FEB 2021 23:59

FDA-CBER-2022-1614-2936620

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 FEB 2021 08:33:36
Patient Cloud Open Date & Time	18 FEB 2021 00:01
Patient Cloud Close Date & Time	22 FEB 2021 23:59

FDA-CBER-2022-1614-2936621

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 MAR 2021 11:56:21
Patient Cloud Open Date & Time	25 FEB 2021 00:01
Patient Cloud Close Date & Time	01 MAR 2021 23:59

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 MAR 2021 21:44:20
Patient Cloud Open Date & Time	04 MAR 2021 00:01
Patient Cloud Close Date & Time	08 MAR 2021 23:59

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33

TIMEPOINT	DAY 208
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 MAR 2021 09:33:19
Patient Cloud Open Date & Time	11 MAR 2021 00:01
Patient Cloud Close Date & Time	15 MAR 2021 23:59

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 MAR 2021 07:36:39
Patient Cloud Open Date & Time	18 MAR 2021 00:01
Patient Cloud Close Date & Time	22 MAR 2021 23:59

US3672163
Folder: Cosmetic Injections and Dermal Fillers
Form: Cosmetic Injection_ Dermal Filler eDiary
Generated On: 10 Jun 2021 09:21:33

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		01 MAR 2021 11:56:32

FDA-CBER-2022-1614-2936626

US3672163
Folder: Safety Call Day 85 (1)
Form: Safety Call
Data signed: (b) (4) **05 Mar 2021 17:57:43**
Generated On: 10 Jun 2021 09:21:33

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

FDA-CBER-2022-1614-2936627

US3672163
Folder: Safety Call Day 85 (1)
Form: Continuing
Data signed: (b) (4) **05 Mar 2021 17:57:43**
Generated On: 10 Jun 2021 09:21:33

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

FDA-CBER-2022-1614-2936628

US3672163
Folder: Safety Call Day 119 (1)
Form: Safety Call
Data signed: (b) (4) **05 Mar 2021 17:57:43**
Generated On: 10 Jun 2021 09:21:33

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	10 DEC 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments	
If Contact Not Made, please provide Comments	

FDA-CBER-2022-1614-2936629

US3672163
Folder: Safety Call Day 119 (1)
Form: Continuing
Data signed: (b) (4) **05 Mar 2021 17:57:43**
Generated On: 10 Jun 2021 09:21:33

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

FDA-CBER-2022-1614-2936630

US3672163
Folder: Safety Call Day 149 (1)
Form: Safety Call
Data signed: (b) (4) **05 Mar 2021 17:57:43**
Generated On: 10 Jun 2021 09:21:33

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	12 JAN 2021
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments	
If Contact Not Made, please provide Comments	

FDA-CBER-2022-1614-2936631

US3672163
Folder: Safety Call Day 149 (1)
Form: Continuing
Data signed: (b) (4) **05 Mar 2021 17:57:43**
Generated On: 10 Jun 2021 09:21:33

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

FDA-CBER-2022-1614-2936632

US3672163
Folder: Safety Call Day 179 (1)
Form: Safety Call
Data signed: (b) (4) **05 Mar 2021 17:57:43**
Generated On: 10 Jun 2021 09:21:33

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

FDA-CBER-2022-1614-2936633

US3672163
Folder: Safety Call Day 179 (1)
Form: Continuing
Data signed: (b) (4) **05 Mar 2021 17:57:43**
Generated On: 10 Jun 2021 09:21:33

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

FDA-CBER-2022-1614-2936634

US3672163
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Data signed: (b) (4) **05 Mar 2021 17:57:43**
Generated On: 10 Jun 2021 09:21:33

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	1 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	VISIT4

FDA-CBER-2022-1614-2936635

US3672163
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Data signed: (b) (4) **16 Apr 2021 15:06:07**
Generated On: 10 Jun 2021 09:21:33

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

FDA-CBER-2022-1614-2936636

US3672163
Folder: Visit 4 Day 209 (1)
Form: Physical Examination
Data signed: (b) (4) **05 Mar 2021 17:57:43**
Generated On: 10 Jun 2021 09:21:33

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-2022-1614-2936637

US3672163
Folder: Visit 4 Day 209 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **05 Mar 2021 17:57:43**
Generated On: 10 Jun 2021 09:21:33

Was the sample collected?	Yes ☑ No ☐
Collection date *(dd MMM yyyy)*	1 MAR 2021
Collection time *(00:00-23:59)*	16:20 (24 HR)
Collection date and time (derived)	1 MAR 2021 16:20

FDA-CBER-2022-1614-2936638

US3672163
Folder: Visit 4 Day 209 (1)
Form: Continuing
Data signed: (b) (4) **05 Mar 2021 17:57:43**
Generated On: 10 Jun 2021 09:21:33

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

FDA-CBER-2022-1614-2936639

US3672163
Folder: Covid-19 Assessment (1)
Form: COVID-19 Contact
Generated On: 10 Jun 2021 09:21:33

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-2022-1614-2936640

Generate Next COVID-19 Assessment	Yes ☐ No ☐

US3672163
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Data signed: (b) (4) **05 Mar 2021 17:57:43**
Generated On: 10 Jun 2021 09:21:33

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	19 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	UNBLND_DECIDE

FDA-CBER-2022-1614-2936642

US3672163
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Data signed: (b) (4) **16 Apr 2021 15:06:07**
Generated On: 10 Jun 2021 09:21:33

Date of updated informed consent *(dd MMM yyyy)*	19 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes ■ No ☐
Under what version of the Protocol was the Participant unblinded?	Amendment 5 ☐ Amendment 6 or later ■
Date of unblinding *(dd MMM yyyy)*	19 JAN 2021
Participant randomization assignment	mRNA-1273 ■ Placebo ☐
Actual Dose 1	mRNA-1273 ■ Placebo ☐ Not Administered ☐
Actual Dose 2	mRNA-1273 ☐ Placebo ☐ Not Administered ■
Will participant receive mRNA-1273?	Yes ☐ No ■
Placebo Only Flag	
Continuing with mRNA-1273	

FDA-CBER-2022-1614-2936643

US3672163
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **05 Mar 2021 17:57:43**
Generated On: 10 Jun 2021 09:21:33

Was the sample collected?	Yes ☑ No ☐
Collection date *(dd MMM yyyy)*	19 JAN 2021
Collection time *(00:00-23:59)*	16:47 (24 HR)
Collection date and time (derived)	19 JAN 2021 16:47

FDA-CBER-2022-1614-2936644

US3672163
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Data signed: (b) (4) **05 Mar 2021 17:57:43**
Generated On: 10 Jun 2021 09:21:33

Was the sample collected?	Yes ☑ No ☐
Collection date *(dd MMM yyyy)*	19 JAN 2021
Collection time *(00:00 - 23:59)*	16:28
Collection Date and Time (derived)	19 JAN 2021 16:28

FDA-CBER-2022-1614-2936645

US3672163
Folder: Unscheduled 27 Aug 2020
Form: Unscheduled Visit Assessment
Data signed: (b) (4) **05 Mar 2021 17:57:43**
Generated On: 10 Jun 2021 09:21:33

Visit Date	27 AUG 2020
Please check all assessments that apply for this visit	
Physical Exam	True
Vital Signs	False
Immunogenicity Assessment	False
Pregnancy Test	False

FDA-CBER-2022-1614-2936646

US3672163
Folder: Unscheduled 27 Aug 2020
Form: Physical Examination
Data signed: (b) (4) **05 Mar 2021 17:57:43**
Generated On: 10 Jun 2021 09:21:33

Was the physical examination performed?	Yes ■ No ☐
Date of examination *(dd MMM yyyy)*	27 AUG 2020

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

FDA-CBER-2022-1614-2936647

US3672163
Folder: Adverse Events
Form: Adverse Events Summary
Data signed: (b) (4) **05 Mar 2021 17:57:43**
Generated On: 10 Jun 2021 09:21:33

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

If Yes, enter details on the Adverse Events form.

FDA-CBER-2022-1614-2936648

US3672163
Folder: Adverse Events
Form: Adverse Events (2)
Data signed: (b) (4) **05 Mar 2021 17:57:42**
Generated On: 10 Jun 2021 09:21:33

AEID	
Adverse event	RIGHT ARM ERYTHEMA (URTICARIAL)
Was this a medically-attended AE?	Yes ■ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ■
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ■
Start date *(dd MMM yyyy)*	26 AUG 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ■
If not Ongoing, end date *(dd MMM yyyy)*	1 OCT 2020
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ■ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ■
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐

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

US3672163
Folder: Adverse Events
Form: Adverse Events (3)
Data signed: (b) (4) **05 Mar 2021 17:57:42**
Generated On: 10 Jun 2021 09:21:33

AEID	
Adverse event	RIGHT ARM INDURATION
Was this a medically-attended AE?	Yes ■ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ■
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ■
Start date *(dd MMM yyyy)*	26 AUG 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ■
If not Ongoing, end date *(dd MMM yyyy)*	2 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
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☐ Related ■ Not Applicable ☐
Relationship to Study Procedure	Not Related ■ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product Withdrawn ■ Not Applicable ☐
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ■ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Ony)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3672163
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination Summary
Data signed: (b) (4) **05 Mar 2021 17:57:43**
Generated On: 10 Jun 2021 09:21:33

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

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

FDA-CBER-2022-1614-2936653

US3672163
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Data signed: (b) (4) **05 Mar 2021 17:57:43**
Generated On: 10 Jun 2021 09:21:33

Name of Medication	CHOLESTRYRAMINE
Prophylaxis	Yes ☐ No ■
Indication	INTERRMITTENT POST - CHOLECYSTERECTOMY DIARRHEA
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 ☐

FDA-CBER-2022-1614-2936654

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

US3672163
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Data signed: (b) (4) **05 Mar 2021 17:57:43**
Generated On: 10 Jun 2021 09:21:33

Name of Medication	PAROXETINE
Prophylaxis	Yes ☐ No ■
Indication	VASOMOTOR SYMPTOMS
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-2022-1614-2936656

	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 2017
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 ■

US3672163
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Data signed: (b) (4) **05 Mar 2021 17:57:43**
Generated On: 10 Jun 2021 09:21:33

Name of Medication	BENADRYL
Prophylaxis	Yes ☐ No ■
Indication	SEASONAL ALLERGIES
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-2022-1614-2936658

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

US3672163
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Data signed: (b) (4) **05 Mar 2021 17:57:43**
Generated On: 10 Jun 2021 09:21:33

Name of Medication	INFLUENZA VACCINE
Prophylaxis	Yes ■ No ☐
Indication	INFLUENZA PROPHYLAXIS
Dose per administration	1
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ■
If dose unit is Other, specify	INJECTION
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-2022-1614-2936660

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

US3672163
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures Summary
Data signed: (b) (4) **16 Apr 2021 15:06:07**
Generated On: 10 Jun 2021 09:21:33

Were any concomitant procedures performed?	Yes ☐
	No ■

If yes, please complete Concomitant Procedures form.

FDA-CBER-2022-1614-2936662

US3672163
Folder: End of Study (1)
Form: Dosing Discontinuation
Data signed: (b) (4) **05 Mar 2021 17:57:43**
Generated On: 10 Jun 2021 09:21:33

Date of dosing discontinuation (dd MMM yyyy)	28 AUG 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	AE#2, AE# 3

FDA-CBER-2022-1614-2936663

US3672163
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Data signed: (b) (4) **16 Apr 2021 15:06:07**
Generated On: 10 Jun 2021 09:21:33

Date of study discontinuation/completion *(dd MMM yyyy)*	01 MAR 2021
Reason for discontinuation	AE (specify) ■ SAE (specify) ☐ Complete ☐ Death ☐ Lost To Follow-up ☐ Physician decision (specify) ☐ Pregnancy ☐ Protocol deviation (specify) ☐ Study Terminated By Sponsor ☐ Withdrawal of consent by participant (specify) ☐ Other ☐
If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify	AE#2 & AE#3
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-2022-1614-2936664

Audit

US3672163 (Prod: Coastal Carolina Research Center)

US3672163
Form: Participant Creation
Generated On: 10 Jun 2021 09:21:33
Participant ID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 14:36:03
User entered 'US3672163'	RWS_ENDPOINT ENDPOINT (b) (4)	18 Aug 2020 17:04:18

FDA-CBER-2022-1614-2936666

US3672163
Form: Participant Creation
Generated On: 10 Jun 2021 09:21:33

mRNA-1273-P301 Completion Guidelines

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27

FDA-CBER-2022-1614-2936667

US3672163
Folder: Screening
Form: Visit Date
Generated On: 10 Jun 2021 09:21:33
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:46:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Aug 2020 17:28:02

FDA-CBER-2022-1614-2936668

US3672163
Folder: Screening
Form: Visit Date
Generated On: 10 Jun 2021 09:21:33
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:46:47
User entered '18 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	18 Aug 2020 17:04:19

FDA-CBER-2022-1614-2936669

US3672163
Folder: Screening
Form: Visit Date
Generated On: 10 Jun 2021 09:21:33
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:46:47
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	18 Aug 2020 17:28:02

US3672163
Folder: Screening
Form: Visit Date
Generated On: 10 Jun 2021 09:21:33
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User entered 'SCRN'	System	18 Aug 2020 17:28:02

US3672163
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:21:33
Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:46:50
User entered (b) (6) 1964'	RWS_ENDPOINT ENDPOINT (b) (4)	18 Aug 2020 17:04:20

FDA-CBER-2022-1614-2936672

US3672163
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:21:33
Age

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:46:50
User entered '56'	(b) (4), (b) (6)	18 Aug 2020 17:28:10

US3672163
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:21:33
Age Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User entered 'YEARS'	System	18 Aug 2020 17:28:10

US3672163
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:21:33
Age (Derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User entered '56'	System	18 Aug 2020 17:28:21

FDA-CBER-2022-1614-2936675

US3672163
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:21:33
Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:46:50
User entered 'Female (F)'	(b) (4), (b) (6)	18 Aug 2020 17:28:10

FDA-CBER-2022-1614-2936676

US3672163
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:21:33
Ethnicity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:46:50
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	18 Aug 2020 17:28:10

US3672163
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:21:33
White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:46:50
User entered '1'	(b) (4), (b) (6)	18 Aug 2020 17:28:10

US3672163
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:21:33
Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:46:50
User entered '0'	(b) (4), (b) (6)	18 Aug 2020 17:28:10

US3672163
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:21:33
Asian

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:46:50
User entered '0'	(b) (4), (b) (6)	18 Aug 2020 17:28:10

US3672163
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:21:33
American Indian or Alaska Native

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:46:50
User entered '0'	(b) (4), (b) (6)	18 Aug 2020 17:28:10

US3672163
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:21:33
Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:46:50
User entered '0'	(b) (4), (b) (6)	18 Aug 2020 17:28:10

US3672163
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:21:33
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:46:50
User entered '0'	(b) (4), (b) (6)	18 Aug 2020 17:28:10

US3672163
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:21:33
If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:46:50
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 17:28:10

US3672163
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:21:33
Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:46:50
User entered '0'	(b) (4), (b) (6)	18 Aug 2020 17:28:10

US3672163
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:21:33
Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:46:50
User entered '0'	(b) (4), (b) (6)	18 Aug 2020 17:28:10

FDA-CBER-2022-1614-2936686

US3672163
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 09:21:33
Date of Informed Consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:47:37
User entered '18 Aug 2020'	(b) (4), (b) (6)	18 Aug 2020 17:28:21

US3672163
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 09:21:33
Month and Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User entered 'Aug 2020'	System	18 Aug 2020 17:28:21

FDA-CBER-2022-1614-2936688

US3672163
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 09:21:33
Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User entered '2020'	System	18 Aug 2020 17:28:21

FDA-CBER-2022-1614-2936689

US3672163
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 09:21:33
Protocol Version

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:47:37
User entered 'Amendment 2 (2)'	(b) (4), (b) (6)	18 Aug 2020 17:28:21

FDA-CBER-2022-1614-2936690

US3672163
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 09:21:33
Was participant enrolled in the study?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:47:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Aug 2020 17:28:21

US3672163
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 09:21:33
If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:47:37
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 17:28:21

FDA-CBER-2022-1614-2936692

US3672163
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 09:21:33
If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:47:37
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 17:28:21

US3672163
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 09:21:33
Was this participant screened previously?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:47:37
User entered 'No (N)'	(b) (4), (b) (6)	18 Aug 2020 17:28:21

FDA-CBER-2022-1614-2936694

US3672163
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 09:21:33
If Yes, previous participant number

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:47:37
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	18 Aug 2020 17:04:19

FDA-CBER-2022-1614-2936695

US3672163
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 09:21:33
Enrollment Trigger

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User entered '1'	System	18 Aug 2020 17:28:24

FDA-CBER-2022-1614-2936696

US3672163
Folder: Screening
Form: Inclusion/Exclusion Criteria Summary
Generated On: 10 Jun 2021 09:21:33
Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:47:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Aug 2020 17:28:24

US3672163
Folder: Screening
Form: Medical History Summary
Generated On: 10 Jun 2021 09:21:33
Were any significant conditions reported?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:47:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 15:17:02

US3672163
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 09:21:33
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 18:20:24
User coded data point as SOC: Surgical and medical procedures, HLGT: Hepatobiliary therapeutic procedures, HLT: Biliary tract and gallbladder therapeutic procedures, PT: Cholecystectomy, LLT: Cholecystectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Oct 2020 22:00:29
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Oct 2020 22:00:29
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 15:36:27
Data point term sent to Coder	System	22 Oct 2020 12:30:33
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 12:30:14
DataPoint Un-verified.	(b) (4), (b) (6)	22 Oct 2020 12:30:10
Coding entries removed.	(b) (4), (b) (6)	22 Oct 2020 12:30:10
User entered 'CHOLECYSTECTOMY due to gallstones' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Oct 2020 12:30:10
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 09:36:45
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:48:06
User coded data point as SOC: Surgical and medical procedures, HLGT: Hepatobiliary therapeutic procedures, HLT: Biliary tract and gallbladder therapeutic procedures, PT: Cholecystectomy, LLT: Cholecystectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 15:19:21

US3672163
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 09:21:33
Condition

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 15:19:21
Data point term sent to Coder	System	20 Aug 2020 15:18:27
User entered 'CHOLECYSTECTOMY'	(b) (4), (b) (6)	20 Aug 2020 15:17:51

US3672163
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 09:21:33
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:48:06
User entered 'UN UNK 2018'	(b) (4), (b) (6)	20 Aug 2020 15:17:51

FDA-CBER-2022-1614-2936701

US3672163
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 09:21:33
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:48:06
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 15:17:51

US3672163
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 09:21:33
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:48:06
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 15:17:51

US3672163
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 09:21:33
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:48:06
User entered 'UN UNK 2018'	(b) (4), (b) (6)	20 Aug 2020 15:17:51

FDA-CBER-2022-1614-2936704

US3672163
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 09:21:33
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:48:06
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 15:17:51

US3672163
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 09:21:33
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User entered 'Jan 2018'	System	20 Aug 2020 15:17:51

US3672163
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 09:21:33
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User entered '2018'	System	20 Aug 2020 15:17:51

US3672163
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 09:21:33
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User entered 'Jan 2018'	System	20 Aug 2020 15:17:51

FDA-CBER-2022-1614-2936708

US3672163
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 09:21:33
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User entered '2018'	System	20 Aug 2020 15:17:51

FDA-CBER-2022-1614-2936709

US3672163
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 09:21:33
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:48:06
User coded data point as SOC: Nervous system disorders, HLGT: Neuromuscular disorders, HLT: Autonomic nervous system disorders, PT: Autonomic nervous system imbalance, LLT: Instability vasomotor - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 12:14:46
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 12:14:46
Data point term sent to Coder	System	20 Aug 2020 15:19:32
User entered 'VASOMOTOR SYMPTOMS'	(b) (4), (b) (6)	20 Aug 2020 15:19:06

US3672163
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 09:21:33
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:48:06
User entered 'UN UNK 2017'	(b) (4), (b) (6)	20 Aug 2020 15:19:06

US3672163
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 09:21:33
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:48:06
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 15:19:06

US3672163
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 09:21:33
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:48:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 15:19:06

US3672163
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 09:21:33
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:48:06
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 15:19:06

FDA-CBER-2022-1614-2936714

US3672163
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 09:21:33
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:48:06
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 15:19:06

US3672163
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 09:21:33
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User entered 'Jan 2017'	System	20 Aug 2020 15:19:06

FDA-CBER-2022-1614-2936716

US3672163
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 09:21:33
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User entered '2017'	System	20 Aug 2020 15:19:06

FDA-CBER-2022-1614-2936717

US3672163
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 09:21:33
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User entered empty.	System	20 Aug 2020 15:19:06

FDA-CBER-2022-1614-2936718

US3672163
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 09:21:33
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User entered empty.	System	20 Aug 2020 15:19:06

US3672163
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 09:21:33
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:48:06
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 15:21:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 15:21:22
Data point term sent to Coder	System	20 Aug 2020 15:20:33
User entered 'SEASONAL ALLERGIES'	(b) (4), (b) (6)	20 Aug 2020 15:19:45

US3672163
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 09:21:33
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:48:06
User entered 'UN UNK 2016'	(b) (4), (b) (6)	20 Aug 2020 15:19:45

US3672163
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 09:21:33
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:48:06
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 15:19:45

US3672163
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 09:21:33
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:48:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 15:19:45

US3672163
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 09:21:33
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:48:06
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 15:19:45

FDA-CBER-2022-1614-2936724

US3672163
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 09:21:33
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:48:06
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 15:19:45

US3672163
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 09:21:33
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User entered 'Jan 2016'	System	20 Aug 2020 15:19:45

US3672163
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 09:21:33
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User entered '2016'	System	20 Aug 2020 15:19:45

FDA-CBER-2022-1614-2936727

US3672163
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 09:21:33
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User entered empty.	System	20 Aug 2020 15:19:45

FDA-CBER-2022-1614-2936728

US3672163
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 09:21:33
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User entered empty.	System	20 Aug 2020 15:19:45

FDA-CBER-2022-1614-2936729

US3672163
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 09:21:33
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:48:06
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Procedural related injuries and complications NEC, HLT: Gastrointestinal and hepatobiliary procedural complications, PT: Post procedural diarrhoea, LLT: Post procedural diarrhea - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Sep 2020 20:41:37
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Sep 2020 20:41:37
Data point term sent to Coder	System	20 Aug 2020 15:21:37
User entered 'INTERMITTENT POST CHOLECYSTECTOMY DIARRHEA'	(b) (4), (b) (6)	20 Aug 2020 15:20:48

US3672163
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 09:21:33
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:48:06
User entered 'UN UNK 2018'	(b) (4), (b) (6)	20 Aug 2020 15:20:48

FDA-CBER-2022-1614-2936731

US3672163
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 09:21:33
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:48:06
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 15:20:48

US3672163
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 09:21:33
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:48:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 15:20:48

US3672163
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 09:21:33
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:48:06
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 15:20:48

FDA-CBER-2022-1614-2936734

US3672163
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 09:21:33
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:48:06
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 15:20:48

US3672163
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 09:21:33
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User entered 'Jan 2018'	System	20 Aug 2020 15:20:48

FDA-CBER-2022-1614-2936736

US3672163
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 09:21:33
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User entered '2018'	System	20 Aug 2020 15:20:48

FDA-CBER-2022-1614-2936737

US3672163
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 09:21:33
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User entered empty.	System	20 Aug 2020 15:20:48

US3672163
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 09:21:33
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User entered empty.	System	20 Aug 2020 15:20:48

US3672163
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 09:21:33
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:48:06
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 15:22:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 15:22:26
Data point term sent to Coder	System	20 Aug 2020 15:21:39
User entered 'POST MENOPAUSAL'	(b) (4), (b) (6)	20 Aug 2020 15:21:15

US3672163
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 09:21:33
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:48:06
User entered 'UN UNK 2015'	(b) (4), (b) (6)	20 Aug 2020 15:21:15

FDA-CBER-2022-1614-2936741

US3672163
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 09:21:33
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:48:06
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 15:21:15

FDA-CBER-2022-1614-2936742

US3672163
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 09:21:33
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:48:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 15:21:15

FDA-CBER-2022-1614-2936743

US3672163
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 09:21:33
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:48:06
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 15:21:15

FDA-CBER-2022-1614-2936744

US3672163
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 09:21:33
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:48:06
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 15:21:15

US3672163
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 09:21:33
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User entered 'Jan 2015'	System	20 Aug 2020 15:21:15

FDA-CBER-2022-1614-2936746

US3672163
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 09:21:33
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User entered '2015'	System	20 Aug 2020 15:21:15

FDA-CBER-2022-1614-2936747

US3672163
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 09:21:33
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User entered empty.	System	20 Aug 2020 15:21:15

FDA-CBER-2022-1614-2936748

US3672163
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 09:21:33
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User entered empty.	System	20 Aug 2020 15:21:15

FDA-CBER-2022-1614-2936749

US3672163
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:21:33
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:48:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 15:22:14

FDA-CBER-2022-1614-2936750

US3672163
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:21:33
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:48:34
User entered '18 Aug 2020'	(b) (4), (b) (6)	20 Aug 2020 15:22:14

US3672163
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:21:33
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:48:34
User entered '13:08'	(b) (4), (b) (6)	20 Aug 2020 15:22:14

FDA-CBER-2022-1614-2936752

US3672163
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:21:33
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User entered '18 Aug 2020 13:08'	System	20 Aug 2020 15:22:14

US3672163
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:21:33
Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:48:34
User entered '157.6' cm	(b) (4), (b) (6)	20 Aug 2020 15:22:14
DataPoint set to visible.	System	18 Aug 2020 17:28:24

US3672163
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:21:33
Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:48:34
User entered '91.9' kg	(b) (4), (b) (6)	20 Aug 2020 15:22:14
DataPoint set to visible.	System	18 Aug 2020 17:28:24

US3672163
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:21:33
BMI *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
Amendment Manager: User entered '37.00012'	System	17 Sep 2020 00:12:18
User entered '37.0'	System	20 Aug 2020 15:22:14
DataPoint set to visible.	System	18 Aug 2020 17:28:24

US3672163
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:21:33
BMI units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User entered 'kg/m2'	System	20 Aug 2020 15:22:14
DataPoint set to visible.	System	18 Aug 2020 17:28:24

US3672163
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:21:33
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:48:34
User entered missing code ND - Not Done.	(b) (4), (b) (6)	20 Aug 2020 15:22:14

US3672163
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:21:33
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:48:34
User entered 'Other (Other)'	(b) (4), (b) (6)	20 Aug 2020 15:22:14

US3672163
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:21:33
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:48:34
User entered missing code ND - Not Done.	(b) (4), (b) (6)	20 Aug 2020 15:22:14

FDA-CBER-2022-1614-2936760

US3672163
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:21:33
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:48:34
User entered missing code ND - Not Done.	(b) (4), (b) (6)	20 Aug 2020 15:22:14

US3672163
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:21:33
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User entered 'bpm'	System	20 Aug 2020 15:22:14

US3672163
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:21:33
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:48:34
User entered missing code ND - Not Done.	(b) (4), (b) (6)	20 Aug 2020 15:22:14

US3672163
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:21:33
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User entered 'breaths/min'	System	20 Aug 2020 15:22:14

US3672163
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:21:33
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:48:34
User entered missing code ND - Not Done.	(b) (4), (b) (6)	20 Aug 2020 15:22:14

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US3672163
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:21:33
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User entered 'mmHg'	System	20 Aug 2020 15:22:14

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US3672163
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:21:33
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:48:34
User entered missing code ND - Not Done.	(b) (4), (b) (6)	20 Aug 2020 15:22:14

US3672163
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:21:33
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User entered 'mmHg'	System	20 Aug 2020 15:22:14

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US3672163
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:21:33
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27

FDA-CBER-2022-1614-2936769

US3672163
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:21:33
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27

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US3672163
Folder: Screening
Form: Physical Examination
Generated On: 10 Jun 2021 09:21:33
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:48:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 15:22:30

US3672163
Folder: Screening
Form: Physical Examination
Generated On: 10 Jun 2021 09:21:33
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	24 Sep 2020 10:55:22
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	14 Sep 2020 19:40:59
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:48:45
User entered '18 Aug 2020'	(b) (4), (b) (6)	20 Aug 2020 15:22:30

US3672163
Folder: Screening
Form: Childbearing Potential
Generated On: 10 Jun 2021 09:21:33
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:48:54
User entered '18 Aug 2020'	(b) (4), (b) (6)	20 Aug 2020 15:24:05

US3672163
Folder: Screening
Form: Childbearing Potential
Generated On: 10 Jun 2021 09:21:33
Is the participant of childbearing potential?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:48:54
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 15:24:05

US3672163
Folder: Screening
Form: Childbearing Potential
Generated On: 10 Jun 2021 09:21:33
If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:48:54
User entered 'Post-menopausal (POST-MENOPAUSAL)'	(b) (4), (b) (6)	20 Aug 2020 15:24:05

US3672163
Folder: Screening
Form: Childbearing Potential
Generated On: 10 Jun 2021 09:21:33
If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:48:54
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 15:24:05

US3672163
Folder: Screening
Form: Childbearing Potential
Generated On: 10 Jun 2021 09:21:33
If Surgically sterile, date of surgery *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:48:54
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 15:24:05

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US3672163
Folder: Screening
Form: Childbearing Potential
Generated On: 10 Jun 2021 09:21:33
Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:48:54
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 15:24:05

US3672163
Folder: Screening
Form: Childbearing Potential
Generated On: 10 Jun 2021 09:21:33
If Post-menopausal, date of last menstruation *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:48:54
User entered 'UN UNK 2015'	(b) (4), (b) (6)	20 Aug 2020 15:24:05

US3672163
Folder: Screening
Form: Childbearing Potential
Generated On: 10 Jun 2021 09:21:33
Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:48:54
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 15:24:05

US3672163
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:21:33
Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:49:12
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 15:26:44

US3672163
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:21:33
Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:49:12
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 15:26:44

US3672163
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:21:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:49:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 15:26:44

US3672163
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:21:33
Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:49:12
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 15:26:44

US3672163
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:21:33
Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:49:12
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 15:26:44

US3672163
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:21:33
Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:49:12
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 15:26:44

US3672163
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:21:33
Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:49:12
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 15:26:44

US3672163
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:21:33
Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:49:12
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 15:26:44

US3672163
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:21:33
Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:49:12
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 15:26:44

US3672163
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:21:33
Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:49:12
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 15:26:44

US3672163
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:21:33
Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:49:12
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 15:26:44

US3672163
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:21:33
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:49:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 15:26:44

US3672163
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:21:33
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 15:49:12
User entered (b) (6) VOLUNTEER.'	(b) (4), (b) (6)	20 Aug 2020 15:26:44

US3672163
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:21:33
No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:59:54
User entered '0'	(b) (4), (b) (6) (b) (4)	20 Aug 2020 15:26:44

US3672163
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:21:33
Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:49:12
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 15:26:44

US3672163
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:21:33
Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:49:12
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 15:26:44

US3672163
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:21:33
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:49:12
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 15:26:44

US3672163
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:21:33
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:49:12
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 15:26:44

US3672163
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:21:33
Resides in a single family home (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:49:12
User entered '1'	(b) (4), (b) (6)	20 Aug 2020 15:26:44

US3672163
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:21:33
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:59:54
User entered '1'	(b) (4), (b) (6) (b) (4)	20 Aug 2020 15:26:44

US3672163
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:21:33
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:49:12
User entered 'RESIDENT IN A COMMUNITY WITH ONGOING PERSON TO PERSON TRANSMISSION.'	(b) (4), (b) (6)	20 Aug 2020 15:26:44

US3672163
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 10 Jun 2021 09:21:33
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:49:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Aug 2020 17:28:35

US3672163
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 10 Jun 2021 09:21:33
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:49:27
User entered '18 Aug 2020'	(b) (4), (b) (6)	18 Aug 2020 17:28:35

US3672163
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 10 Jun 2021 09:21:33
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:49:27
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	18 Aug 2020 17:28:35

US3672163
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 10 Jun 2021 09:21:33
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User entered 'VISIT1'	System	18 Aug 2020 17:28:35

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US3672163
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 09:21:33
What was the date of randomization? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:49:32
User entered '18 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	18 Aug 2020 17:24:29

FDA-CBER-2022-1614-2936806

US3672163
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 09:21:33
What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:49:32
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 05:20:25
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 05:20:25
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	18 Aug 2020 17:24:29
User entered '105575' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	18 Aug 2020 17:24:29

US3672163
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 09:21:33
In what Cohort was the participant enrolled?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:49:32
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	18 Aug 2020 17:24:29

FDA-CBER-2022-1614-2936808

US3672163
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 09:21:33
Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:49:32
User entered 'No (N)'	(b) (4), (b) (6)	18 Aug 2020 17:28:43

US3672163
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 09:21:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:49:32
User entered 'No (N)'	(b) (4), (b) (6)	18 Aug 2020 17:28:43

US3672163
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 09:21:33
Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:49:32
User entered 'No (N)'	(b) (4), (b) (6)	18 Aug 2020 17:28:43

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US3672163
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 09:21:33
Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:49:32
User entered 'No (N)'	(b) (4), (b) (6)	18 Aug 2020 17:28:43

US3672163
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 09:21:33
Liver Disease

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:49:32
User entered 'No (N)'	(b) (4), (b) (6)	18 Aug 2020 17:28:43

US3672163
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 09:21:33
Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 18:20:09
User entered 'No (N)'	(b) (4), (b) (6)	22 Oct 2020 12:28:29
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:34:53
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 01:19:31

US3672163
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 09:21:33
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:59:57
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:50:02
User entered missing code ND - Not Done.	(b) (4), (b) (6)	20 Aug 2020 15:28:47

US3672163
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 09:21:33
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:59:57
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:50:02
User entered missing code ND - Not Done.	(b) (4), (b) (6)	20 Aug 2020 15:28:47

US3672163
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 09:21:33
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:57
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:50:02
User entered missing code ND - Not Done.	(b) (4), (b) (6)	20 Aug 2020 15:28:47

FDA-CBER-2022-1614-2936817

US3672163
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 09:21:33
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:59:57
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:50:02
User entered missing code ND - Not Done.	(b) (4), (b) (6)	20 Aug 2020 15:28:47

US3672163
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:21:33
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	20 Aug 2020 15:28:47

US3672163
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:21:33
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:57
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:50:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 15:28:47

FDA-CBER-2022-1614-2936820

US3672163
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:21:33
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:57
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:50:02
User entered '18 Aug 2020'	(b) (4), (b) (6)	20 Aug 2020 15:28:47

US3672163
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:21:33
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:57
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:50:02
User entered '13:08'	(b) (4), (b) (6)	20 Aug 2020 15:28:47

US3672163
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:21:33
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User entered '18 Aug 2020 13:08'	System	20 Aug 2020 15:28:47

FDA-CBER-2022-1614-2936823

US3672163
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:21:33
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:59:57
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:50:02
User entered '99.0' F	(b) (4), (b) (6)	20 Aug 2020 15:28:47

US3672163
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:21:33
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:57
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:50:02
User entered 'Oral (Oral)'	(b) (4), (b) (6)	20 Aug 2020 15:28:47

US3672163
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:21:33
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:57
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:50:02
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 15:28:47

US3672163
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:21:33
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:59:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 15:50:02
User closed query 'Data is required. Please provide.' (Site from System).	System	20 Aug 2020 15:30:19
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	20 Aug 2020 15:30:19
User entered '61' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Aug 2020 15:30:19
User opened query 'Data is required. Please provide.' (Site from System).	System	20 Aug 2020 15:28:47
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 15:28:47

US3672163
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:21:33
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User entered 'bpm'	System	20 Aug 2020 15:30:19
User entered empty.	System	20 Aug 2020 15:28:47

FDA-CBER-2022-1614-2936828

US3672163
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:21:33
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:59:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 15:50:02
User closed query 'Data is required. Please provide.' (Site from System).	System	20 Aug 2020 15:30:19
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	20 Aug 2020 15:30:19
User entered '16' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Aug 2020 15:30:19
User opened query 'Data is required. Please provide.' (Site from System).	System	20 Aug 2020 15:28:47
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 15:28:47

US3672163
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:21:33
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User entered 'breaths/min'	System	20 Aug 2020 15:30:19
User entered empty.	System	20 Aug 2020 15:28:47

FDA-CBER-2022-1614-2936830

US3672163
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:21:33
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:59:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 15:50:02
User closed query 'Data is required. Please provide.' (Site from System).	System	20 Aug 2020 15:30:19
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	20 Aug 2020 15:30:19
User entered '115' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Aug 2020 15:30:19
User opened query 'Data is required. Please provide.' (Site from System).	System	20 Aug 2020 15:28:47
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 15:28:47

US3672163
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:21:33
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User entered 'mmHg'	System	20 Aug 2020 15:30:19
User entered empty.	System	20 Aug 2020 15:28:47

FDA-CBER-2022-1614-2936832

US3672163
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:21:33
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:59:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 15:50:02
User closed query 'Data is required. Please provide.' (Site from System).	System	20 Aug 2020 15:30:19
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	20 Aug 2020 15:30:19
User entered '84' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Aug 2020 15:30:19
User opened query 'Data is required. Please provide.' (Site from System).	System	20 Aug 2020 15:28:47
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 15:28:47

US3672163
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:21:33
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User entered 'mmHg'	System	20 Aug 2020 15:30:19
User entered empty.	System	20 Aug 2020 15:28:47

US3672163
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 09:21:33
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:59:57
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:50:02
User entered missing code ND - Not Done.	(b) (4), (b) (6)	20 Aug 2020 15:28:47

US3672163
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 09:21:33
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:59:57
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:50:02
User entered missing code ND - Not Done.	(b) (4), (b) (6)	20 Aug 2020 15:28:47

US3672163
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:21:33
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	20 Aug 2020 15:28:47

FDA-CBER-2022-1614-2936837

US3672163
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:21:33
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:57
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:50:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 15:28:47

US3672163
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:21:33
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:57
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:50:02
User entered '18 Aug 2020'	(b) (4), (b) (6)	20 Aug 2020 15:28:47

US3672163
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:21:33
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:59:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 15:50:02
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:20:22
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'TIME IS CONFIRMED. CORRECT.' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 15:29:28
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	System	20 Aug 2020 15:28:47
User entered '14:23'	(b) (4), (b) (6)	20 Aug 2020 15:28:47

US3672163
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:21:33
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User entered '18 Aug 2020 14:23'	System	20 Aug 2020 15:28:47

FDA-CBER-2022-1614-2936841

US3672163
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:21:33
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:57
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:50:02
User entered '98.5' F	(b) (4), (b) (6)	20 Aug 2020 15:28:47

US3672163
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:21:33
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:57
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:50:02
User entered 'Oral (Oral)'	(b) (4), (b) (6)	20 Aug 2020 15:28:47

FDA-CBER-2022-1614-2936843

US3672163
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:21:33
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:57
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:50:02
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 15:28:47

FDA-CBER-2022-1614-2936844

US3672163
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:21:33
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:59:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 15:50:02
User entered '56' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Aug 2020 15:31:29
User closed query 'Data is required. Please provide.' (Site from System).	System	20 Aug 2020 15:29:49
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	20 Aug 2020 15:29:49
User entered '61' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Aug 2020 15:29:49
User opened query 'Data is required. Please provide.' (Site from System).	System	20 Aug 2020 15:28:47
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 15:28:47

FDA-CBER-2022-1614-2936845

US3672163
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:21:33
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User entered 'bpm'	System	20 Aug 2020 15:29:49
User entered empty.	System	20 Aug 2020 15:28:47

US3672163
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:21:33
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:59:57
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:50:02
User entered '14' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Aug 2020 15:31:29
User closed query 'Data is required. Please provide.' (Site from System).	System	20 Aug 2020 15:29:49
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	20 Aug 2020 15:29:49
User entered '16' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Aug 2020 15:29:49
User opened query 'Data is required. Please provide.' (Site from System).	System	20 Aug 2020 15:28:47
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 15:28:47

US3672163
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:21:33
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User entered 'breaths/min'	System	20 Aug 2020 15:29:49
User entered empty.	System	20 Aug 2020 15:28:47

FDA-CBER-2022-1614-2936848

US3672163
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:21:33
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:59:57
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:50:02
User entered '110' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Aug 2020 15:31:29
User closed query 'Data is required. Please provide.' (Site from System).	System	20 Aug 2020 15:29:49
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	20 Aug 2020 15:29:49
User entered '115' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Aug 2020 15:29:49
User opened query 'Data is required. Please provide.' (Site from System).	System	20 Aug 2020 15:28:47
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 15:28:47

FDA-CBER-2022-1614-2936849

US3672163
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:21:33
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User entered 'mmHg'	System	20 Aug 2020 15:29:49
User entered empty.	System	20 Aug 2020 15:28:47

FDA-CBER-2022-1614-2936850

US3672163
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:21:33
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:59:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 15:50:02
User entered '76' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Aug 2020 15:31:29
User closed query 'Data is required. Please provide.' (Site from System).	System	20 Aug 2020 15:29:49
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	20 Aug 2020 15:29:49
User entered '84' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Aug 2020 15:29:49
User opened query 'Data is required. Please provide.' (Site from System).	System	20 Aug 2020 15:28:47
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 15:28:47

FDA-CBER-2022-1614-2936851

US3672163
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:21:33
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User entered 'mmHg'	System	20 Aug 2020 15:29:49
User entered empty.	System	20 Aug 2020 15:28:47

US3672163
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 10 Jun 2021 09:21:33
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:50:06
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 15:32:27

US3672163
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 10 Jun 2021 09:21:33
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:50:06
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 15:32:27

FDA-CBER-2022-1614-2936854

US3672163
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:21:33
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:50:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Aug 2020 17:59:45

FDA-CBER-2022-1614-2936855

US3672163
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:21:33
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:50:13
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 17:59:45

US3672163
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:21:33
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:50:13
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 17:59:45

US3672163
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:21:33
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User entered 'MRNA-1273 OR PLACEBO'	System	18 Aug 2020 17:59:45

US3672163
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:21:33
What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:50:13
User entered '18 Aug 2020'	(b) (4), (b) (6)	18 Aug 2020 17:59:45

US3672163
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:21:33
What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:50:13
User entered '13:47'	(b) (4), (b) (6)	18 Aug 2020 17:59:45

FDA-CBER-2022-1614-2936860

US3672163
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:21:33
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User entered '18 Aug 2020 13:47'	System	18 Aug 2020 17:59:45

US3672163
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:21:33
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:50:13
User entered 'Right Arm (RIGHT ARM)'	(b) (4), (b) (6)	18 Aug 2020 17:59:45

US3672163
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:21:33
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:50:13
User entered 'ONCE'	System	18 Aug 2020 17:59:45

US3672163
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:21:33
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User entered 'INTRAMUSCULAR'	System	18 Aug 2020 17:59:45

US3672163
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:21:33
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:50:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 15:33:32

FDA-CBER-2022-1614-2936865

US3672163
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:21:33
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:50:18
User entered '18 Aug 2020'	(b) (4), (b) (6)	20 Aug 2020 15:33:32

US3672163
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:21:33
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:50:18
User entered '13:22'	(b) (4), (b) (6)	20 Aug 2020 15:33:32

US3672163
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:21:33
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User entered '18 Aug 2020 13:22'	System	20 Aug 2020 15:33:32

US3672163
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab
Generated On: 10 Jun 2021 09:21:33
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:50:35
User entered '18 Aug 2020'	(b) (4), (b) (6)	20 Aug 2020 15:33:51

US3672163
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 09:21:33
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	20 Aug 2020 15:33:51

US3672163
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 09:21:33
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:50:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 15:33:51

US3672163
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 09:21:33
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:50:35
User entered '12:54'	(b) (4), (b) (6)	20 Aug 2020 15:33:51

US3672163
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 09:21:33
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User entered '18 Aug 2020 12:54'	System	20 Aug 2020 15:33:51

US3672163
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 09:21:33
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	20 Aug 2020 15:33:51

FDA-CBER-2022-1614-2936874

US3672163
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 09:21:33
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:50:35
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 15:33:51

US3672163
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 09:21:33
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:50:35
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 15:33:51

US3672163
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 09:21:33
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User entered empty.	System	20 Aug 2020 15:33:51

US3672163
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 10 Jun 2021 09:21:33
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:50:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 15:33:56

FDA-CBER-2022-1614-2936878

US3672163
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 10 Jun 2021 09:21:33
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User entered '1'	System	20 Aug 2020 15:33:56

US3672163
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:21:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
Data entry locked.	System	18 Aug 2020 17:59:45
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Aug 2020 17:59:45

FDA-CBER-2022-1614-2936880

US3672163
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:21:33
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-18T14:20:00', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '4d28a935-8fd1-4493-9e6d-8b3bae13dc04'	System	18 Aug 2020 18:20:37
User entered 'Yes (Y)'	System	18 Aug 2020 18:20:37

FDA-CBER-2022-1614-2936881

US3672163
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:21:33
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-18T14:20:06', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '4d28a935-8fd1-4493-9e6d-8b3bae13dc04'	System	18 Aug 2020 18:20:37
User entered '98.5'	System	18 Aug 2020 18:20:37

FDA-CBER-2022-1614-2936882

US3672163
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:21:33
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-18T14:20:13', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '4d28a935-8fd1-4493-9e6d-8b3bae13dc04'	System	18 Aug 2020 18:20:37
User entered 'No (N)'	System	18 Aug 2020 18:20:37

US3672163
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:21:33
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-18T14:20:19', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '4d28a935-8fd1-4493-9e6d-8b3bae13dc04'	System	18 Aug 2020 18:20:37
User entered '18 Aug 2020 14:20'	System	18 Aug 2020 18:20:37

FDA-CBER-2022-1614-2936884

US3672163
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:21:33
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
User entered '18 Aug 2020 14:07'	System	18 Aug 2020 17:59:45

FDA-CBER-2022-1614-2936885

US3672163
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:21:33
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
User entered '18 Aug 2020 16:37'	System	18 Aug 2020 17:59:45

FDA-CBER-2022-1614-2936886

US3672163
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:21:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
Data entry locked.	System	18 Aug 2020 17:59:45
User entered 'Day 1, after vaccination (at home)'	System	18 Aug 2020 17:59:45

FDA-CBER-2022-1614-2936887

US3672163
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:21:33
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-18T17:33:46', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '409fe886-94ad-4b00-bab4-ee8b94a94532'	System	18 Aug 2020 21:34:03
User entered 'Yes (Y)'	System	18 Aug 2020 21:34:03

FDA-CBER-2022-1614-2936888

US3672163
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:21:33
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-18T17:33:51', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '409fe886-94ad-4b00-bab4-ee8b94a94532'	System	18 Aug 2020 21:34:03
User entered '97.9'	System	18 Aug 2020 21:34:03

US3672163
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:21:33
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-18T17:33:56', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '409fe886-94ad-4b00-bab4-ee8b94a94532'	System	18 Aug 2020 21:34:03
User entered 'No (N)'	System	18 Aug 2020 21:34:03

US3672163
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:21:33
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-18T17:34:00', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '409fe886-94ad-4b00-bab4-ee8b94a94532'	System	18 Aug 2020 21:34:03
User entered '18 Aug 2020 17:34'	System	18 Aug 2020 21:34:03

FDA-CBER-2022-1614-2936891

US3672163
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:21:33
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
User entered '18 Aug 2020 17:32'	System	18 Aug 2020 17:59:45

FDA-CBER-2022-1614-2936892

US3672163
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:21:33
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
User entered '19 Aug 2020 11:59'	System	18 Aug 2020 17:59:45

FDA-CBER-2022-1614-2936893

US3672163
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:21:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
Data entry locked.	System	18 Aug 2020 17:59:45
User entered 'Day 2'	System	18 Aug 2020 17:59:45

FDA-CBER-2022-1614-2936894

US3672163
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:21:33
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-19T22:32:50', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '9051ebdc-8aae-4b23-8f59-2d00ede1de6c'	System	20 Aug 2020 02:33:11
User entered 'Yes (Y)'	System	20 Aug 2020 02:33:11

FDA-CBER-2022-1614-2936895

US3672163
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:21:33
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-19T22:32:56', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '9051ebdc-8aae-4b23-8f59-2d00ede1de6c'	System	20 Aug 2020 02:33:11
User entered '98.6'	System	20 Aug 2020 02:33:11

FDA-CBER-2022-1614-2936896

US3672163
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:21:33
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-19T22:33:06', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '9051ebdc-8aae-4b23-8f59-2d00ede1de6c'	System	20 Aug 2020 02:33:11
User entered 'No (N)'	System	20 Aug 2020 02:33:11

US3672163
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:21:33
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-19T22:33:09', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '9051ebdc-8aae-4b23-8f59-2d00ede1de6c'	System	20 Aug 2020 02:33:11
User entered '19 Aug 2020 22:33'	System	20 Aug 2020 02:33:11

FDA-CBER-2022-1614-2936898

US3672163
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:21:33
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
User entered '19 Aug 2020 12:00'	System	18 Aug 2020 17:59:45

FDA-CBER-2022-1614-2936899

US3672163
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:21:33
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
User entered '20 Aug 2020 11:59'	System	18 Aug 2020 17:59:45

FDA-CBER-2022-1614-2936900

US3672163
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:21:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
Data entry locked.	System	18 Aug 2020 17:59:45
User entered 'Day 3'	System	18 Aug 2020 17:59:45

FDA-CBER-2022-1614-2936901

US3672163
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:21:33
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-20T17:53:16', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '08ab5037-7479-4639-89e2-4babc5a388e7'	System	20 Aug 2020 21:53:32
User entered 'Yes (Y)'	System	20 Aug 2020 21:53:32

US3672163
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:21:33
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-20T17:53:21', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '08ab5037-7479-4639-89e2-4babc5a388e7'	System	20 Aug 2020 21:53:32
User entered '98.0'	System	20 Aug 2020 21:53:32

US3672163
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:21:33
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-20T17:53:25', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '08ab5037-7479-4639-89e2-4babc5a388e7'	System	20 Aug 2020 21:53:32
User entered 'No (N)'	System	20 Aug 2020 21:53:32

US3672163
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:21:33
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-20T17:53:28', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '08ab5037-7479-4639-89e2-4babc5a388e7'	System	20 Aug 2020 21:53:32
User entered '20 Aug 2020 17:53'	System	20 Aug 2020 21:53:32

US3672163
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:21:33
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
User entered '20 Aug 2020 12:00'	System	18 Aug 2020 17:59:45

FDA-CBER-2022-1614-2936906

US3672163
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:21:33
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
User entered '21 Aug 2020 11:59'	System	18 Aug 2020 17:59:45

FDA-CBER-2022-1614-2936907

US3672163
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:21:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
Data entry locked.	System	18 Aug 2020 17:59:45
User entered 'Day 4'	System	18 Aug 2020 17:59:45

FDA-CBER-2022-1614-2936908

US3672163
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:21:33
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-21T18:09:38', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: 'd644bc60-64d3-45de-b367-4005dbe2fd66'	System	21 Aug 2020 22:09:54
User entered 'Yes (Y)'	System	21 Aug 2020 22:09:54

FDA-CBER-2022-1614-2936909

US3672163
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:21:33
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-21T18:09:44', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: 'd644bc60-64d3-45de-b367-4005dbe2fd66'	System	21 Aug 2020 22:09:54
User entered '98.0'	System	21 Aug 2020 22:09:54

FDA-CBER-2022-1614-2936910

US3672163
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:21:33
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-21T18:09:47', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: 'd644bc60-64d3-45de-b367-4005dbe2fd66'	System	21 Aug 2020 22:09:54
User entered 'No (N)'	System	21 Aug 2020 22:09:54

FDA-CBER-2022-1614-2936911

US3672163
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:21:33
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-21T18:09:50', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: 'd644bc60-64d3-45de-b367-4005dbe2fd66'	System	21 Aug 2020 22:09:54
User entered '21 Aug 2020 18:09'	System	21 Aug 2020 22:09:54

FDA-CBER-2022-1614-2936912

US3672163
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:21:33
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
User entered '21 Aug 2020 12:00'	System	18 Aug 2020 17:59:45

FDA-CBER-2022-1614-2936913

US3672163
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:21:33
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
User entered '22 Aug 2020 11:59'	System	18 Aug 2020 17:59:45

FDA-CBER-2022-1614-2936914

US3672163
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:21:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
Data entry locked.	System	18 Aug 2020 17:59:45
User entered 'Day 5'	System	18 Aug 2020 17:59:45

FDA-CBER-2022-1614-2936915

US3672163
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:21:33
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-22T17:42:49', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '6abf9025-1c67-48be-9d3c-8b32453f5a3e'	System	22 Aug 2020 21:43:06
User entered 'Yes (Y)'	System	22 Aug 2020 21:43:06

FDA-CBER-2022-1614-2936916

US3672163
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:21:33
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-22T17:42:53', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '6abf9025-1c67-48be-9d3c-8b32453f5a3e'	System	22 Aug 2020 21:43:06
User entered '96.5'	System	22 Aug 2020 21:43:06

FDA-CBER-2022-1614-2936917

US3672163
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:21:33
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-22T17:43:00', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '6abf9025-1c67-48be-9d3c-8b32453f5a3e'	System	22 Aug 2020 21:43:06
User entered 'No (N)'	System	22 Aug 2020 21:43:06

FDA-CBER-2022-1614-2936918

US3672163
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:21:33
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-22T17:43:02', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '6abf9025-1c67-48be-9d3c-8b32453f5a3e'	System	22 Aug 2020 21:43:06
User entered '22 Aug 2020 17:43'	System	22 Aug 2020 21:43:06

FDA-CBER-2022-1614-2936919

US3672163
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:21:33
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
User entered '22 Aug 2020 12:00'	System	18 Aug 2020 17:59:45

FDA-CBER-2022-1614-2936920

US3672163
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:21:33
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
User entered '23 Aug 2020 11:59'	System	18 Aug 2020 17:59:45

FDA-CBER-2022-1614-2936921

US3672163
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:21:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
Data entry locked.	System	18 Aug 2020 17:59:45
User entered 'Day 6'	System	18 Aug 2020 17:59:45

FDA-CBER-2022-1614-2936922

US3672163
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:21:33
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-24T08:27:27', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '94171806-2090-439f-92cf-c24221212a9d'	System	24 Aug 2020 12:27:51
User entered 'Yes (Y)'	System	24 Aug 2020 12:27:51

FDA-CBER-2022-1614-2936923

US3672163
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:21:33
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-24T08:27:40', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '94171806-2090-439f-92cf-c24221212a9d'	System	24 Aug 2020 12:27:51
User entered '97.4'	System	24 Aug 2020 12:27:51

FDA-CBER-2022-1614-2936924

US3672163
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:21:33
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-24T08:27:45', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '94171806-2090-439f-92cf-c24221212a9d'	System	24 Aug 2020 12:27:51
User entered 'No (N)'	System	24 Aug 2020 12:27:51

FDA-CBER-2022-1614-2936925

US3672163
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:21:33
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-24T08:27:48', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '94171806-2090-439f-92cf-c24221212a9d'	System	24 Aug 2020 12:27:51
User entered '24 Aug 2020 08:27'	System	24 Aug 2020 12:27:51

US3672163
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:21:33
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
User entered '23 Aug 2020 12:00'	System	18 Aug 2020 17:59:45

FDA-CBER-2022-1614-2936927

US3672163
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:21:33
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
User entered '24 Aug 2020 11:59'	System	18 Aug 2020 17:59:45

FDA-CBER-2022-1614-2936928

US3672163
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:21:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
Data entry locked.	System	18 Aug 2020 17:59:45
User entered 'Day 7'	System	18 Aug 2020 17:59:45

FDA-CBER-2022-1614-2936929

US3672163
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:21:33
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-24T18:35:08', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: 'ea735fea-9424-446c-bafd-c9ababd955ea'	System	24 Aug 2020 22:35:29
User entered 'Yes (Y)'	System	24 Aug 2020 22:35:29

FDA-CBER-2022-1614-2936930

US3672163
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:21:33
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-24T18:35:12', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: 'ea735fea-9424-446c-bafd-c9ababd955ea'	System	24 Aug 2020 22:35:29
User entered '97.6'	System	24 Aug 2020 22:35:29

US3672163
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:21:33
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-24T18:35:21', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: 'ea735fea-9424-446c-bafd-c9ababd955ea'	System	24 Aug 2020 22:35:29
User entered 'No (N)'	System	24 Aug 2020 22:35:29

US3672163
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:21:33
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-24T18:35:23', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: 'ea735fea-9424-446c-bafd-c9ababd955ea'	System	24 Aug 2020 22:35:29
User entered '24 Aug 2020 18:35'	System	24 Aug 2020 22:35:29

US3672163
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:21:33
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
User entered '24 Aug 2020 12:00'	System	18 Aug 2020 17:59:45

FDA-CBER-2022-1614-2936934

US3672163
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:21:33
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
User entered '25 Aug 2020 11:59'	System	18 Aug 2020 17:59:45

FDA-CBER-2022-1614-2936935

US3672163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:21:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
Data entry locked.	System	18 Aug 2020 17:59:45
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Aug 2020 17:59:45

US3672163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:21:33
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-18T14:20:32', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: 'd766bfea-bdc1-477f-8db3-84006c19553a'	System	18 Aug 2020 18:21:07
User entered 'None (1)'	System	18 Aug 2020 18:21:07

US3672163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:21:33
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-18T14:20:41', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: 'd766bfea-bdc1-477f-8db3-84006c19553a'	System	18 Aug 2020 18:21:07
User entered 'No (N)'	System	18 Aug 2020 18:21:07

US3672163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:21:33
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-18T14:20:46', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: 'd766bfea-bdc1-477f-8db3-84006c19553a'	System	18 Aug 2020 18:21:07
User entered 'No (N)'	System	18 Aug 2020 18:21:07

FDA-CBER-2022-1614-2936939

US3672163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:21:33
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-18T14:20:56', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: 'd766bfea-bdc1-477f-8db3-84006c19553a'	System	18 Aug 2020 18:21:07
User entered 'None (1)'	System	18 Aug 2020 18:21:07

US3672163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:21:33
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-18T14:21:03', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: 'd766bfea-bdc1-477f-8db3-84006c19553a'	System	18 Aug 2020 18:21:07
User entered '18 Aug 2020 14:21'	System	18 Aug 2020 18:21:07

FDA-CBER-2022-1614-2936941

US3672163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:21:33
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
User entered '18 Aug 2020 14:07'	System	18 Aug 2020 17:59:45

FDA-CBER-2022-1614-2936942

US3672163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:21:33
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
User entered '18 Aug 2020 16:37'	System	18 Aug 2020 17:59:45

FDA-CBER-2022-1614-2936943

US3672163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:21:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
Data entry locked.	System	18 Aug 2020 17:59:45
User entered 'Day 1, after vaccination (at home)'	System	18 Aug 2020 17:59:45

FDA-CBER-2022-1614-2936944

US3672163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:21:33
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-18T17:34:28', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '649b8273-2b37-407e-a503-6a948741cdda'	System	18 Aug 2020 21:35:07
User entered 'Does not interfere with activity (2)'	System	18 Aug 2020 21:35:07

FDA-CBER-2022-1614-2936945

US3672163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:21:33
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-18T17:34:39', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '649b8273-2b37-407e-a503-6a948741cdda'	System	18 Aug 2020 21:35:07
User entered 'No (N)'	System	18 Aug 2020 21:35:07

US3672163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:21:33
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-18T17:34:50', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '649b8273-2b37-407e-a503-6a948741cdda'	System	18 Aug 2020 21:35:07
User entered 'No (N)'	System	18 Aug 2020 21:35:07

US3672163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:21:33
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-18T17:35:01', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '649b8273-2b37-407e-a503-6a948741cdda'	System	18 Aug 2020 21:35:07
User entered 'None (1)'	System	18 Aug 2020 21:35:07

US3672163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:21:33
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-18T17:35:04', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '649b8273-2b37-407e-a503-6a948741cdda'	System	18 Aug 2020 21:35:07
User entered '18 Aug 2020 17:35'	System	18 Aug 2020 21:35:07

FDA-CBER-2022-1614-2936949

US3672163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:21:33
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
User entered '18 Aug 2020 17:32'	System	18 Aug 2020 17:59:45

FDA-CBER-2022-1614-2936950

US3672163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:21:33
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
User entered '19 Aug 2020 11:59'	System	18 Aug 2020 17:59:45

FDA-CBER-2022-1614-2936951

US3672163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:21:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
Data entry locked.	System	18 Aug 2020 17:59:45
User entered 'Day 2'	System	18 Aug 2020 17:59:45

US3672163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:21:33
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-19T22:33:16', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '6615657b-4ce4-4d4e-86d4-3682cd9f458d'	System	20 Aug 2020 02:33:34
User entered 'Does not interfere with activity (2)'	System	20 Aug 2020 02:33:34

US3672163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:21:33
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-19T22:33:19', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '6615657b-4ce4-4d4e-86d4-3682cd9f458d'	System	20 Aug 2020 02:33:34
User entered 'No (N)'	System	20 Aug 2020 02:33:34

US3672163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:21:33
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-19T22:33:22', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '6615657b-4ce4-4d4e-86d4-3682cd9f458d'	System	20 Aug 2020 02:33:34
User entered 'No (N)'	System	20 Aug 2020 02:33:34

US3672163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:21:33
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-19T22:33:28', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '6615657b-4ce4-4d4e-86d4-3682cd9f458d'	System	20 Aug 2020 02:33:34
User entered 'None (1)'	System	20 Aug 2020 02:33:34

US3672163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:21:33
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-19T22:33:31', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '6615657b-4ce4-4d4e-86d4-3682cd9f458d'	System	20 Aug 2020 02:33:34
User entered '19 Aug 2020 22:33'	System	20 Aug 2020 02:33:34

US3672163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:21:33
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
User entered '19 Aug 2020 12:00'	System	18 Aug 2020 17:59:45

FDA-CBER-2022-1614-2936958

US3672163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:21:33
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
User entered '20 Aug 2020 11:59'	System	18 Aug 2020 17:59:45

FDA-CBER-2022-1614-2936959

US3672163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:21:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
Data entry locked.	System	18 Aug 2020 17:59:45
User entered 'Day 3'	System	18 Aug 2020 17:59:45

FDA-CBER-2022-1614-2936960

US3672163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:21:33
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-20T17:53:54', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: 'f2d88d96-5fe8-47aa-8ebc-647032b301b0'	System	20 Aug 2020 21:55:01
User entered 'Does not interfere with activity (2)'	System	20 Aug 2020 21:55:01

FDA-CBER-2022-1614-2936961

US3672163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:21:33
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-20T17:53:57', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: 'f2d88d96-5fe8-47aa-8ebc-647032b301b0'	System	20 Aug 2020 21:55:01
User entered 'Yes (Y)'	System	20 Aug 2020 21:55:01

FDA-CBER-2022-1614-2936962

US3672163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:21:33
Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-20T17:54:25', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: 'f2d88d96-5fe8-47aa-8ebc-647032b301b0'	System	20 Aug 2020 21:55:01
User entered '25'	System	20 Aug 2020 21:55:01

US3672163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:21:33
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-20T17:54:33', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: 'f2d88d96-5fe8-47aa-8ebc-647032b301b0'	System	20 Aug 2020 21:55:01
User entered 'Yes (Y)'	System	20 Aug 2020 21:55:01

FDA-CBER-2022-1614-2936964

US3672163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:21:33
Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-20T17:54:41', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: 'f2d88d96-5fe8-47aa-8ebc-647032b301b0'	System	20 Aug 2020 21:55:01
User entered '25'	System	20 Aug 2020 21:55:01

US3672163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:21:33
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-20T17:54:51', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: 'f2d88d96-5fe8-47aa-8ebc-647032b301b0'	System	20 Aug 2020 21:55:01
User entered 'None (1)'	System	20 Aug 2020 21:55:01

FDA-CBER-2022-1614-2936966

US3672163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:21:33
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-20T17:54:58', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: 'f2d88d96-5fe8-47aa-8ebc-647032b301b0'	System	20 Aug 2020 21:55:01
User entered '20 Aug 2020 17:54'	System	20 Aug 2020 21:55:01

FDA-CBER-2022-1614-2936967

US3672163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:21:33
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
User entered '20 Aug 2020 12:00'	System	18 Aug 2020 17:59:45

FDA-CBER-2022-1614-2936968

US3672163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:21:33
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
User entered '21 Aug 2020 11:59'	System	18 Aug 2020 17:59:45

FDA-CBER-2022-1614-2936969

US3672163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:21:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
Data entry locked.	System	18 Aug 2020 17:59:45
User entered 'Day 4'	System	18 Aug 2020 17:59:45

FDA-CBER-2022-1614-2936970

US3672163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:21:33
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-21T18:10:10', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: 'c6436644-1a55-4e0f-9b54-cf7d3a62d456'	System	21 Aug 2020 22:10:32
User entered 'Does not interfere with activity (2)'	System	21 Aug 2020 22:10:32

US3672163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:21:33
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-21T18:10:13', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: 'c6436644-1a55-4e0f-9b54-cf7d3a62d456'	System	21 Aug 2020 22:10:32
User entered 'No (N)'	System	21 Aug 2020 22:10:32

FDA-CBER-2022-1614-2936972

US3672163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:21:33
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-21T18:10:21', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: 'c6436644-1a55-4e0f-9b54-cf7d3a62d456'	System	21 Aug 2020 22:10:32
User entered 'No (N)'	System	21 Aug 2020 22:10:32

FDA-CBER-2022-1614-2936973

US3672163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:21:33
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-21T18:10:25', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: 'c6436644-1a55-4e0f-9b54-cf7d3a62d456'	System	21 Aug 2020 22:10:32
User entered 'None (1)'	System	21 Aug 2020 22:10:32

FDA-CBER-2022-1614-2936974

US3672163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:21:33
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-21T18:10:28', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: 'c6436644-1a55-4e0f-9b54-cf7d3a62d456'	System	21 Aug 2020 22:10:32
User entered '21 Aug 2020 18:10'	System	21 Aug 2020 22:10:32

FDA-CBER-2022-1614-2936975

US3672163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:21:33
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
User entered '21 Aug 2020 12:00'	System	18 Aug 2020 17:59:45

FDA-CBER-2022-1614-2936976

US3672163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:21:33
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
User entered '22 Aug 2020 11:59'	System	18 Aug 2020 17:59:45

FDA-CBER-2022-1614-2936977

US3672163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:21:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
Data entry locked.	System	18 Aug 2020 17:59:45
User entered 'Day 5'	System	18 Aug 2020 17:59:45

FDA-CBER-2022-1614-2936978

US3672163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:21:33
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-22T17:43:06', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '9aca7140-46a2-40c3-976e-189487f58dea'	System	22 Aug 2020 21:43:43
User entered 'None (1)'	System	22 Aug 2020 21:43:43

US3672163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:21:33
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-22T17:43:09', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '9aca7140-46a2-40c3-976e-189487f58dea'	System	22 Aug 2020 21:43:43
User entered 'No (N)'	System	22 Aug 2020 21:43:43

US3672163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:21:33
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-22T17:43:17', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '9aca7140-46a2-40c3-976e-189487f58dea'	System	22 Aug 2020 21:43:43
User entered 'Yes (Y)'	System	22 Aug 2020 21:43:43

US3672163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:21:33
Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-22T17:43:32', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '9aca7140-46a2-40c3-976e-189487f58dea'	System	22 Aug 2020 21:43:43
User entered '2'	System	22 Aug 2020 21:43:43

FDA-CBER-2022-1614-2936982

US3672163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:21:33
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-22T17:43:39', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '9aca7140-46a2-40c3-976e-189487f58dea'	System	22 Aug 2020 21:43:43
User entered 'None (1)'	System	22 Aug 2020 21:43:43

US3672163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:21:33
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-22T17:43:42', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '9aca7140-46a2-40c3-976e-189487f58dea'	System	22 Aug 2020 21:43:43
User entered '22 Aug 2020 17:43'	System	22 Aug 2020 21:43:43

FDA-CBER-2022-1614-2936984

US3672163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:21:33
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
User entered '22 Aug 2020 12:00'	System	18 Aug 2020 17:59:45

FDA-CBER-2022-1614-2936985

US3672163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:21:33
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
User entered '23 Aug 2020 11:59'	System	18 Aug 2020 17:59:45

FDA-CBER-2022-1614-2936986

US3672163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:21:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
Data entry locked.	System	18 Aug 2020 17:59:45
User entered 'Day 6'	System	18 Aug 2020 17:59:45

US3672163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:21:33
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-24T08:27:55', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: 'd8f0de90-f332-4cba-bbc7-16a85f47a4e9'	System	24 Aug 2020 12:28:08
User entered 'None (1)'	System	24 Aug 2020 12:28:08

FDA-CBER-2022-1614-2936988

US3672163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:21:33
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-24T08:27:58', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: 'd8f0de90-f332-4cba-bbc7-16a85f47a4e9'	System	24 Aug 2020 12:28:08
User entered 'No (N)'	System	24 Aug 2020 12:28:08

US3672163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:21:33
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-24T08:28:01', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: 'd8f0de90-f332-4cba-bbc7-16a85f47a4e9'	System	24 Aug 2020 12:28:08
User entered 'No (N)'	System	24 Aug 2020 12:28:08

FDA-CBER-2022-1614-2936990

US3672163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:21:33
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-24T08:28:04', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: 'd8f0de90-f332-4cba-bbc7-16a85f47a4e9'	System	24 Aug 2020 12:28:08
User entered 'None (1)'	System	24 Aug 2020 12:28:08

FDA-CBER-2022-1614-2936991

US3672163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:21:33
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-24T08:28:06', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: 'd8f0de90-f332-4cba-bbc7-16a85f47a4e9'	System	24 Aug 2020 12:28:08
User entered '24 Aug 2020 08:28'	System	24 Aug 2020 12:28:08

FDA-CBER-2022-1614-2936992

US3672163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:21:33
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
User entered '23 Aug 2020 12:00'	System	18 Aug 2020 17:59:45

FDA-CBER-2022-1614-2936993

US3672163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:21:33
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
User entered '24 Aug 2020 11:59'	System	18 Aug 2020 17:59:45

FDA-CBER-2022-1614-2936994

US3672163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:21:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
Data entry locked.	System	18 Aug 2020 17:59:45
User entered 'Day 7'	System	18 Aug 2020 17:59:45

FDA-CBER-2022-1614-2936995

US3672163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:21:33
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-24T18:35:27', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '88fb3627-cd15-4b9b-8014-c37337e053b4'	System	24 Aug 2020 22:35:40
User entered 'None (1)'	System	24 Aug 2020 22:35:40

FDA-CBER-2022-1614-2936996

US3672163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:21:33
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-24T18:35:29', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '88fb3627-cd15-4b9b-8014-c37337e053b4'	System	24 Aug 2020 22:35:40
User entered 'No (N)'	System	24 Aug 2020 22:35:40

US3672163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:21:33
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-24T18:35:31', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '88fb3627-cd15-4b9b-8014-c37337e053b4'	System	24 Aug 2020 22:35:40
User entered 'No (N)'	System	24 Aug 2020 22:35:40

US3672163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:21:33
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-24T18:35:33', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '88fb3627-cd15-4b9b-8014-c37337e053b4'	System	24 Aug 2020 22:35:40
User entered 'None (1)'	System	24 Aug 2020 22:35:40

US3672163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:21:33
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-24T18:35:36', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '88fb3627-cd15-4b9b-8014-c37337e053b4'	System	24 Aug 2020 22:35:40
User entered '24 Aug 2020 18:35'	System	24 Aug 2020 22:35:40

FDA-CBER-2022-1614-2937000

US3672163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:21:33
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
User entered '24 Aug 2020 12:00'	System	18 Aug 2020 17:59:45

FDA-CBER-2022-1614-2937001

US3672163
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:21:33
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
User entered '25 Aug 2020 11:59'	System	18 Aug 2020 17:59:45

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:21:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
Data entry locked.	System	18 Aug 2020 17:59:45
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Aug 2020 17:59:45

FDA-CBER-2022-1614-2937003

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:21:33
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-18T14:21:27', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '18226d62-c0dc-4f46-8f38-233fc2e5ce57'	System	18 Aug 2020 18:22:08
User entered 'None (0)'	System	18 Aug 2020 18:22:08

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:21:33
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-18T14:21:32', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '18226d62-c0dc-4f46-8f38-233fc2e5ce57'	System	18 Aug 2020 18:22:08
User entered 'None (0)'	System	18 Aug 2020 18:22:08

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:21:33
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-18T14:21:36', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '18226d62-c0dc-4f46-8f38-233fc2e5ce57'	System	18 Aug 2020 18:22:08
User entered 'None (0)'	System	18 Aug 2020 18:22:08

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:21:33
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-18T14:21:42', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '18226d62-c0dc-4f46-8f38-233fc2e5ce57'	System	18 Aug 2020 18:22:08
User entered 'None (0)'	System	18 Aug 2020 18:22:08

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:21:33
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-18T14:21:48', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '18226d62-c0dc-4f46-8f38-233fc2e5ce57'	System	18 Aug 2020 18:22:08
User entered 'None (0)'	System	18 Aug 2020 18:22:08

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:21:33
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-18T14:21:51', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '18226d62-c0dc-4f46-8f38-233fc2e5ce57'	System	18 Aug 2020 18:22:08
User entered 'None (0)'	System	18 Aug 2020 18:22:08

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:21:33
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-18T14:21:57', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '18226d62-c0dc-4f46-8f38-233fc2e5ce57'	System	18 Aug 2020 18:22:08
User entered 'No (N)'	System	18 Aug 2020 18:22:08

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:21:33
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-18T14:22:02', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '18226d62-c0dc-4f46-8f38-233fc2e5ce57'	System	18 Aug 2020 18:22:08
User entered '18 Aug 2020 14:22'	System	18 Aug 2020 18:22:08

FDA-CBER-2022-1614-2937011

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:21:33
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
User entered '18 Aug 2020 14:07'	System	18 Aug 2020 17:59:45

FDA-CBER-2022-1614-2937012

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:21:33
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
User entered '18 Aug 2020 16:37'	System	18 Aug 2020 17:59:45

FDA-CBER-2022-1614-2937013

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:21:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
Data entry locked.	System	18 Aug 2020 17:59:45
User entered 'Day 1, after vaccination (at home)'	System	18 Aug 2020 17:59:45

FDA-CBER-2022-1614-2937014

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:21:33
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-18T17:35:25', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '0de1f4b0-76b9-46df-92db-104935593429'	System	18 Aug 2020 21:36:07
User entered 'None (0)'	System	18 Aug 2020 21:36:07

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:21:33
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-18T17:35:38', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '0de1f4b0-76b9-46df-92db-104935593429'	System	18 Aug 2020 21:36:07
User entered 'None (0)'	System	18 Aug 2020 21:36:07

FDA-CBER-2022-1614-2937016

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:21:33
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-18T17:35:42', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '0de1f4b0-76b9-46df-92db-104935593429'	System	18 Aug 2020 21:36:07
User entered 'None (0)'	System	18 Aug 2020 21:36:07

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:21:33
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-18T17:35:51', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '0de1f4b0-76b9-46df-92db-104935593429'	System	18 Aug 2020 21:36:07
User entered 'None (0)'	System	18 Aug 2020 21:36:07

FDA-CBER-2022-1614-2937018

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:21:33
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-18T17:35:54', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '0de1f4b0-76b9-46df-92db-104935593429'	System	18 Aug 2020 21:36:07
User entered 'None (0)'	System	18 Aug 2020 21:36:07

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:21:33
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-18T17:35:56', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '0de1f4b0-76b9-46df-92db-104935593429'	System	18 Aug 2020 21:36:07
User entered 'None (0)'	System	18 Aug 2020 21:36:07

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:21:33
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-18T17:36:02', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '0de1f4b0-76b9-46df-92db-104935593429'	System	18 Aug 2020 21:36:07
User entered 'No (N)'	System	18 Aug 2020 21:36:07

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:21:33
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-18T17:36:04', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '0de1f4b0-76b9-46df-92db-104935593429'	System	18 Aug 2020 21:36:07
User entered '18 Aug 2020 17:36'	System	18 Aug 2020 21:36:07

FDA-CBER-2022-1614-2937022

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:21:33
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
User entered '18 Aug 2020 17:32'	System	18 Aug 2020 17:59:45

FDA-CBER-2022-1614-2937023

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:21:33
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
User entered '19 Aug 2020 11:59'	System	18 Aug 2020 17:59:45

FDA-CBER-2022-1614-2937024

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:21:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
Data entry locked.	System	18 Aug 2020 17:59:45
User entered 'Day 2'	System	18 Aug 2020 17:59:45

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:21:33
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-19T22:33:37', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '600d0d36-52ca-4060-a4ec-0e0d70697126'	System	20 Aug 2020 02:34:01
User entered 'No interference with activity (1)'	System	20 Aug 2020 02:34:01

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:21:33
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-19T22:33:40', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '600d0d36-52ca-4060-a4ec-0e0d70697126'	System	20 Aug 2020 02:34:01
User entered 'No interference with activity (1)'	System	20 Aug 2020 02:34:01

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:21:33
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-19T22:33:43', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '600d0d36-52ca-4060-a4ec-0e0d70697126'	System	20 Aug 2020 02:34:01
User entered 'No interference with activity (1)'	System	20 Aug 2020 02:34:01

FDA-CBER-2022-1614-2937028

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:21:33
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-19T22:33:48', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '600d0d36-52ca-4060-a4ec-0e0d70697126'	System	20 Aug 2020 02:34:01
User entered 'None (0)'	System	20 Aug 2020 02:34:01

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:21:33
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-19T22:33:51', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '600d0d36-52ca-4060-a4ec-0e0d70697126'	System	20 Aug 2020 02:34:01
User entered 'None (0)'	System	20 Aug 2020 02:34:01

FDA-CBER-2022-1614-2937030

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:21:33
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-19T22:33:53', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '600d0d36-52ca-4060-a4ec-0e0d70697126'	System	20 Aug 2020 02:34:01
User entered 'None (0)'	System	20 Aug 2020 02:34:01

FDA-CBER-2022-1614-2937031

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:21:33
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-19T22:33:57', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '600d0d36-52ca-4060-a4ec-0e0d70697126'	System	20 Aug 2020 02:34:01
User entered 'No (N)'	System	20 Aug 2020 02:34:01

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:21:33
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-19T22:33:59', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '600d0d36-52ca-4060-a4ec-0e0d70697126'	System	20 Aug 2020 02:34:01
User entered '19 Aug 2020 22:33'	System	20 Aug 2020 02:34:01

FDA-CBER-2022-1614-2937033

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:21:33
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
User entered '19 Aug 2020 12:00'	System	18 Aug 2020 17:59:45

FDA-CBER-2022-1614-2937034

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:21:33
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
User entered '20 Aug 2020 11:59'	System	18 Aug 2020 17:59:45

FDA-CBER-2022-1614-2937035

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:21:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
Data entry locked.	System	18 Aug 2020 17:59:45
User entered 'Day 3'	System	18 Aug 2020 17:59:45

FDA-CBER-2022-1614-2937036

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:21:33
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-20T17:55:03', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '850f478b-cf1c-4306-b1d8-ab39c87e2cd5'	System	20 Aug 2020 21:55:29
User entered 'No interference with activity (1)'	System	20 Aug 2020 21:55:29

FDA-CBER-2022-1614-2937037

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:21:33
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-20T17:55:07', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '850f478b-cf1c-4306-b1d8-ab39c87e2cd5'	System	20 Aug 2020 21:55:29
User entered 'None (0)'	System	20 Aug 2020 21:55:29

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:21:33
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-20T17:55:10', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '850f478b-cf1c-4306-b1d8-ab39c87e2cd5'	System	20 Aug 2020 21:55:29
User entered 'None (0)'	System	20 Aug 2020 21:55:29

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:21:33
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-20T17:55:14', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '850f478b-cf1c-4306-b1d8-ab39c87e2cd5'	System	20 Aug 2020 21:55:29
User entered 'None (0)'	System	20 Aug 2020 21:55:29

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:21:33
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-20T17:55:16', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '850f478b-cf1c-4306-b1d8-ab39c87e2cd5'	System	20 Aug 2020 21:55:29
User entered 'None (0)'	System	20 Aug 2020 21:55:29

FDA-CBER-2022-1614-2937041

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:21:33
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-20T17:55:18', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '850f478b-cf1c-4306-b1d8-ab39c87e2cd5'	System	20 Aug 2020 21:55:29
User entered 'None (0)'	System	20 Aug 2020 21:55:29

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:21:33
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-20T17:55:22', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '850f478b-cf1c-4306-b1d8-ab39c87e2cd5'	System	20 Aug 2020 21:55:29
User entered 'No (N)'	System	20 Aug 2020 21:55:29

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:21:33
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-20T17:55:24', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '850f478b-cf1c-4306-b1d8-ab39c87e2cd5'	System	20 Aug 2020 21:55:29
User entered '20 Aug 2020 17:55'	System	20 Aug 2020 21:55:29

FDA-CBER-2022-1614-2937044

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:21:33
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
User entered '20 Aug 2020 12:00'	System	18 Aug 2020 17:59:45

FDA-CBER-2022-1614-2937045

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:21:33
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
User entered '21 Aug 2020 11:59'	System	18 Aug 2020 17:59:45

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:21:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
Data entry locked.	System	18 Aug 2020 17:59:45
User entered 'Day 4'	System	18 Aug 2020 17:59:45

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:21:33
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-21T18:10:32', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: 'd9412670-ce53-400d-ae0c-67a5c25c9603'	System	21 Aug 2020 22:10:55
User entered 'None (0)'	System	21 Aug 2020 22:10:55

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:21:33
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-21T18:10:35', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: 'd9412670-ce53-400d-ae0c-67a5c25c9603'	System	21 Aug 2020 22:10:55
User entered 'None (0)'	System	21 Aug 2020 22:10:55

FDA-CBER-2022-1614-2937049

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:21:33
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-21T18:10:38', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: 'd9412670-ce53-400d-ae0c-67a5c25c9603'	System	21 Aug 2020 22:10:55
User entered 'None (0)'	System	21 Aug 2020 22:10:55

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:21:33
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-21T18:10:40', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: 'd9412670-ce53-400d-ae0c-67a5c25c9603'	System	21 Aug 2020 22:10:55
User entered 'None (0)'	System	21 Aug 2020 22:10:55

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:21:33
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-21T18:10:43', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: 'd9412670-ce53-400d-ae0c-67a5c25c9603'	System	21 Aug 2020 22:10:55
User entered 'None (0)'	System	21 Aug 2020 22:10:55

FDA-CBER-2022-1614-2937052

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:21:33
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-21T18:10:46', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: 'd9412670-ce53-400d-ae0c-67a5c25c9603'	System	21 Aug 2020 22:10:55
User entered 'None (0)'	System	21 Aug 2020 22:10:55

FDA-CBER-2022-1614-2937053

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:21:33
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-21T18:10:52', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: 'd9412670-ce53-400d-ae0c-67a5c25c9603'	System	21 Aug 2020 22:10:55
User entered 'No (N)'	System	21 Aug 2020 22:10:55

FDA-CBER-2022-1614-2937054

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:21:33
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-21T18:10:53', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: 'd9412670-ce53-400d-ae0c-67a5c25c9603'	System	21 Aug 2020 22:10:55
User entered '21 Aug 2020 18:10'	System	21 Aug 2020 22:10:55

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:21:33
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
User entered '21 Aug 2020 12:00'	System	18 Aug 2020 17:59:45

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:21:33
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
User entered '22 Aug 2020 11:59'	System	18 Aug 2020 17:59:45

FDA-CBER-2022-1614-2937057

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:21:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
Data entry locked.	System	18 Aug 2020 17:59:45
User entered 'Day 5'	System	18 Aug 2020 17:59:45

FDA-CBER-2022-1614-2937058

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:21:33
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-22T17:43:46', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: 'de583395-c523-496e-bbc0-c0756dc9ce44'	System	22 Aug 2020 21:44:03
User entered 'None (0)'	System	22 Aug 2020 21:44:03

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:21:33
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-22T17:43:48', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: 'de583395-c523-496e-bbc0-c0756dc9ce44'	System	22 Aug 2020 21:44:03
User entered 'None (0)'	System	22 Aug 2020 21:44:03

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:21:33
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-22T17:43:50', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: 'de583395-c523-496e-bbc0-c0756dc9ce44'	System	22 Aug 2020 21:44:03
User entered 'None (0)'	System	22 Aug 2020 21:44:03

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:21:33
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-22T17:43:52', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: 'de583395-c523-496e-bbc0-c0756dc9ce44'	System	22 Aug 2020 21:44:03
User entered 'None (0)'	System	22 Aug 2020 21:44:03

FDA-CBER-2022-1614-2937062

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:21:33
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-22T17:43:54', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: 'de583395-c523-496e-bbc0-c0756dc9ce44'	System	22 Aug 2020 21:44:03
User entered 'None (0)'	System	22 Aug 2020 21:44:03

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:21:33
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-22T17:43:56', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: 'de583395-c523-496e-bbc0-c0756dc9ce44'	System	22 Aug 2020 21:44:03
User entered 'None (0)'	System	22 Aug 2020 21:44:03

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:21:33
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-22T17:43:58', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: 'de583395-c523-496e-bbc0-c0756dc9ce44'	System	22 Aug 2020 21:44:03
User entered 'No (N)'	System	22 Aug 2020 21:44:03

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:21:33
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-22T17:44:00', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: 'de583395-c523-496e-bbc0-c0756dc9ce44'	System	22 Aug 2020 21:44:03
User entered '22 Aug 2020 17:44'	System	22 Aug 2020 21:44:03

FDA-CBER-2022-1614-2937066

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:21:33
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
User entered '22 Aug 2020 12:00'	System	18 Aug 2020 17:59:45

FDA-CBER-2022-1614-2937067

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:21:33
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
User entered '23 Aug 2020 11:59'	System	18 Aug 2020 17:59:45

FDA-CBER-2022-1614-2937068

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:21:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
Data entry locked.	System	18 Aug 2020 17:59:45
User entered 'Day 6'	System	18 Aug 2020 17:59:45

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:21:33
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-24T08:28:10', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '26b4daf3-c58a-46fd-b6cb-a6af9fbbd992'	System	24 Aug 2020 12:28:26
User entered 'None (0)'	System	24 Aug 2020 12:28:26

FDA-CBER-2022-1614-2937070

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:21:33
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-24T08:28:11', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '26b4daf3-c58a-46fd-b6cb-a6af9fbbd992'	System	24 Aug 2020 12:28:26
User entered 'None (0)'	System	24 Aug 2020 12:28:26

FDA-CBER-2022-1614-2937071

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:21:33
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-24T08:28:13', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '26b4daf3-c58a-46fd-b6cb-a6af9fbbd992'	System	24 Aug 2020 12:28:26
User entered 'None (0)'	System	24 Aug 2020 12:28:26

FDA-CBER-2022-1614-2937072

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:21:33
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-24T08:28:15', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '26b4daf3-c58a-46fd-b6cb-a6af9fbbd992'	System	24 Aug 2020 12:28:26
User entered 'None (0)'	System	24 Aug 2020 12:28:26

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:21:33
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-24T08:28:17', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '26b4daf3-c58a-46fd-b6cb-a6af9fbbd992'	System	24 Aug 2020 12:28:26
User entered 'None (0)'	System	24 Aug 2020 12:28:26

FDA-CBER-2022-1614-2937074

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:21:33
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-24T08:28:19', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '26b4daf3-c58a-46fd-b6cb-a6af9fbbd992'	System	24 Aug 2020 12:28:26
User entered 'None (0)'	System	24 Aug 2020 12:28:26

FDA-CBER-2022-1614-2937075

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:21:33
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-24T08:28:21', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '26b4daf3-c58a-46fd-b6cb-a6af9fbbd992'	System	24 Aug 2020 12:28:26
User entered 'No (N)'	System	24 Aug 2020 12:28:26

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:21:33
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-24T08:28:23', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '26b4daf3-c58a-46fd-b6cb-a6af9fbbd992'	System	24 Aug 2020 12:28:26
User entered '24 Aug 2020 08:28'	System	24 Aug 2020 12:28:26

FDA-CBER-2022-1614-2937077

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:21:33
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
User entered '23 Aug 2020 12:00'	System	18 Aug 2020 17:59:45

FDA-CBER-2022-1614-2937078

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:21:33
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
User entered '24 Aug 2020 11:59'	System	18 Aug 2020 17:59:45

FDA-CBER-2022-1614-2937079

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:21:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
Data entry locked.	System	18 Aug 2020 17:59:45
User entered 'Day 7'	System	18 Aug 2020 17:59:45

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:21:33
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-24T18:35:39', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '55cc0622-ea62-4a5d-8b09-48aa28d86f25'	System	24 Aug 2020 22:35:55
User entered 'None (0)'	System	24 Aug 2020 22:35:55

FDA-CBER-2022-1614-2937081

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:21:33
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-24T18:35:40', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '55cc0622-ea62-4a5d-8b09-48aa28d86f25'	System	24 Aug 2020 22:35:55
User entered 'None (0)'	System	24 Aug 2020 22:35:55

FDA-CBER-2022-1614-2937082

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:21:33
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-24T18:35:42', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '55cc0622-ea62-4a5d-8b09-48aa28d86f25'	System	24 Aug 2020 22:35:55
User entered 'None (0)'	System	24 Aug 2020 22:35:55

FDA-CBER-2022-1614-2937083

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:21:33
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-24T18:35:43', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '55cc0622-ea62-4a5d-8b09-48aa28d86f25'	System	24 Aug 2020 22:35:55
User entered 'None (0)'	System	24 Aug 2020 22:35:55

FDA-CBER-2022-1614-2937084

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:21:33
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-24T18:35:44', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '55cc0622-ea62-4a5d-8b09-48aa28d86f25'	System	24 Aug 2020 22:35:55
User entered 'None (0)'	System	24 Aug 2020 22:35:55

FDA-CBER-2022-1614-2937085

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:21:33
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-24T18:35:45', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '55cc0622-ea62-4a5d-8b09-48aa28d86f25'	System	24 Aug 2020 22:35:55
User entered 'None (0)'	System	24 Aug 2020 22:35:55

FDA-CBER-2022-1614-2937086

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:21:33
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-24T18:35:47', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '55cc0622-ea62-4a5d-8b09-48aa28d86f25'	System	24 Aug 2020 22:35:55
User entered 'No (N)'	System	24 Aug 2020 22:35:55

FDA-CBER-2022-1614-2937087

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:21:33
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-08-24T18:35:50', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '55cc0622-ea62-4a5d-8b09-48aa28d86f25'	System	24 Aug 2020 22:35:55
User entered '24 Aug 2020 18:35'	System	24 Aug 2020 22:35:55

FDA-CBER-2022-1614-2937088

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:21:33
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
User entered '24 Aug 2020 12:00'	System	18 Aug 2020 17:59:45

FDA-CBER-2022-1614-2937089

US3672163
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:21:33
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
User entered '25 Aug 2020 11:59'	System	18 Aug 2020 17:59:45

FDA-CBER-2022-1614-2937090

US3672163
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:21:33
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:53:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 17:35:29

FDA-CBER-2022-1614-2937091

US3672163
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:21:33
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:53:36
User entered '25 Aug 2020'	(b) (4), (b) (6)	25 Aug 2020 17:35:29

US3672163
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:21:33
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:53:36
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	25 Aug 2020 17:35:29

US3672163
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:21:33
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:53:36
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 17:35:29

US3672163
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:21:33
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:53:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 17:35:38

US3672163
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:21:33
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User entered '1'	System	25 Aug 2020 17:35:38

US3672163
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:21:33
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:53:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 14:13:11

US3672163
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:21:33
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User closed query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	08 Apr 2021 17:53:29
User opened query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	01 Apr 2021 14:30:26
Data hard unlocked.	System	01 Apr 2021 14:30:26
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:53:50
User entered '01 Sep 2020'	(b) (4), (b) (6)	02 Sep 2020 14:13:11

US3672163
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:21:33
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:53:50
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	02 Sep 2020 14:13:11

US3672163
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:21:33
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:53:50
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 14:13:11

US3672163
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:21:33
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 15:53:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 14:13:16

US3672163
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:21:33
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User entered '1'	System	02 Sep 2020 14:13:16

US3672163
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:21:33
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 14:37:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Sep 2020 16:57:03

US3672163
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:21:33
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User closed query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	08 Apr 2021 17:53:29
User opened query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	01 Apr 2021 14:30:26
Data hard unlocked.	System	01 Apr 2021 14:30:26
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 14:37:03
User entered '09 Sep 2020'	(b) (4), (b) (6)	09 Sep 2020 16:57:03

US3672163
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:21:33
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 14:37:03
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	09 Sep 2020 16:57:03

US3672163
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:21:33
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 14:37:03
User entered empty.	(b) (4), (b) (6)	09 Sep 2020 16:57:03

US3672163
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:21:33
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 14:37:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Sep 2020 16:57:08

US3672163
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:21:33
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User entered '1'	System	09 Sep 2020 16:57:08

US3672163
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:21:33
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:57
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 14:48:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 19:40:59

US3672163
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:21:33
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User closed query 'Visit Date is after Date of study discontinuation/completion. Please reconcile.' (Site from System).	System	08 Apr 2021 17:53:29
User opened query 'Visit Date is after Date of study discontinuation/completion. Please reconcile.' (Site from System).	System	01 Apr 2021 14:30:26
Data hard unlocked.	System	01 Apr 2021 14:30:26
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:59:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 14:48:50
User closed query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	15 Sep 2020 08:25:52
Query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' answered with 'visit is within window' (Site from System).	(b) (4), (b) (6)	14 Sep 2020 19:42:09
User opened query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	System	14 Sep 2020 19:40:59
User entered '14 Sep 2020'	(b) (4), (b) (6)	14 Sep 2020 19:40:59

US3672163
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:21:33
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:57
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 14:48:50
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	14 Sep 2020 19:40:59

US3672163
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:21:33
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User entered 'VISIT2'	System	14 Sep 2020 19:40:59

FDA-CBER-2022-1614-2937112

US3672163
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:21:33
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	14 Sep 2020 19:42:36

US3672163
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:21:33
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:57
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 14:49:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 19:42:36

US3672163
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:21:33
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User closed query 'Date of Assessment is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	08 Apr 2021 17:53:29
User opened query 'Date of Assessment is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	01 Apr 2021 14:30:26
Data hard unlocked.	System	01 Apr 2021 14:30:26
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:57
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 14:49:30
User entered '14 Sep 2020'	(b) (4), (b) (6)	14 Sep 2020 19:42:36

US3672163
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:21:33
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:57
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 14:49:30
User entered '15:21'	(b) (4), (b) (6)	14 Sep 2020 19:42:36

FDA-CBER-2022-1614-2937116

US3672163
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:21:33
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User entered '14 Sep 2020 15:21'	System	14 Sep 2020 19:42:36

FDA-CBER-2022-1614-2937117

US3672163
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:21:33
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:57
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 14:49:30
User entered '98.1' F	(b) (4), (b) (6)	14 Sep 2020 19:42:36

US3672163
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:21:33
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:57
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 14:49:30
User entered 'Oral (Oral)'	(b) (4), (b) (6)	14 Sep 2020 19:42:36

FDA-CBER-2022-1614-2937119

US3672163
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:21:33
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:57
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 14:49:30
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 19:42:36

US3672163
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:21:33
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:57
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 14:49:30
User entered '68'	(b) (4), (b) (6)	14 Sep 2020 19:42:36

FDA-CBER-2022-1614-2937121

US3672163
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:21:33
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User entered 'bpm'	System	14 Sep 2020 19:42:36

FDA-CBER-2022-1614-2937122

US3672163
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:21:33
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:57
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 14:49:30
User entered '12'	(b) (4), (b) (6)	14 Sep 2020 19:42:36

US3672163
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:21:33
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User entered 'breaths/min'	System	14 Sep 2020 19:42:36

FDA-CBER-2022-1614-2937124

US3672163
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:21:33
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:57
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 14:49:30
User entered '112'	(b) (4), (b) (6)	14 Sep 2020 19:42:36

US3672163
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:21:33
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User entered 'mmHg'	System	14 Sep 2020 19:42:36

FDA-CBER-2022-1614-2937126

US3672163
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:21:33
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:57
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 14:49:30
User entered '83'	(b) (4), (b) (6)	14 Sep 2020 19:42:36

US3672163
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:21:33
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User entered 'mmHg'	System	14 Sep 2020 19:42:36

FDA-CBER-2022-1614-2937128

US3672163
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:21:33
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	14 Sep 2020 19:42:36

FDA-CBER-2022-1614-2937129

US3672163
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:21:33
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:59:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 14:49:30
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Sep 2020 20:02:07
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Sep 2020 20:02:07
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 20:02:07
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Sep 2020 19:42:36
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 19:42:36

US3672163
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:21:33
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:57
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 14:49:30
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 19:42:36

FDA-CBER-2022-1614-2937131

US3672163
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:21:33
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:57
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 14:49:30
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 19:42:36

US3672163
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:21:33
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User entered empty.	System	14 Sep 2020 19:42:36

FDA-CBER-2022-1614-2937133

US3672163
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:21:33
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:59:57
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 14:49:30
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 19:42:36

US3672163
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:21:33
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:57
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 14:49:30
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 19:42:36

US3672163
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:21:33
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:57
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 14:49:30
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 19:42:36

US3672163
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:21:33
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:57
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 14:49:30
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 19:42:36

FDA-CBER-2022-1614-2937137

US3672163
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:21:33
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User entered empty.	System	14 Sep 2020 19:42:36

US3672163
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:21:33
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:59:57
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 14:49:30
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 19:42:36

US3672163
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:21:33
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User entered empty.	System	14 Sep 2020 19:42:36

US3672163
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:21:33
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:57
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 14:49:30
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 19:42:36

FDA-CBER-2022-1614-2937141

US3672163
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:21:33
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User entered empty.	System	14 Sep 2020 19:42:36

FDA-CBER-2022-1614-2937142

US3672163
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:21:33
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:59:57
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 14:49:30
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 19:42:36

US3672163
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:21:33
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User entered empty.	System	14 Sep 2020 19:42:36

FDA-CBER-2022-1614-2937144

US3672163
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Generated On: 10 Jun 2021 09:21:33
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:57
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 14:49:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 19:42:43

FDA-CBER-2022-1614-2937145

US3672163
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Generated On: 10 Jun 2021 09:21:33
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User closed query 'The Physical Examination Date is greater than Date of study discontinuation/completion. Please review and reconcile.' (Site from System).	System	08 Apr 2021 17:53:29
User opened query 'The Physical Examination Date is greater than Date of study discontinuation/completion. Please review and reconcile.' (Site from System).	System	01 Apr 2021 14:30:26
Data hard unlocked.	System	01 Apr 2021 14:30:26
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:57
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 14:49:43
User entered '14 Sep 2020'	(b) (4), (b) (6)	14 Sep 2020 19:42:43

US3672163
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:21:33
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:57
User closed query 'Per CDM: Please, ensure the 'Dosing Discontinuation' form is completed. ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 07:42:45
Query 'Per CDM: Please, ensure the 'Dosing Discontinuation' form is completed. ' answered with 'dosing discontinuation completed' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 13:25:56
User opened query 'Per CDM: Please, ensure the 'Dosing Discontinuation' form is completed. ' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 12:41:27
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 14:50:44
User entered 'No (N)'	(b) (4), (b) (6)	14 Sep 2020 19:47:17

US3672163
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:21:33
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:59:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 14:50:44
User closed query 'Was study treatment given? is No, however If No, reason not given is not provided. Please review and reconcile.' (Site from System).	System	14 Sep 2020 19:47:25
User entered 'Physician Decision (PHYSICIAN DECISION)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 19:47:25
User opened query 'Was study treatment given? is No, however If No, reason not given is not provided. Please review and reconcile.' (Site from System).	System	14 Sep 2020 19:47:17
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 19:47:17

US3672163
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:21:33
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:59:57
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 18:20:53
User closed query 'Per CDM: As per the CCG page 27, please specify the reason for physician decision. Thank you.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 07:32:23
Query 'Per CDM: As per the CCG page 27, please specify the reason for physician decision. Thank you.' answered with 'physician decision updated' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 13:26:31
DataPoint Un-verified.	(b) (4), (b) (6)	23 Oct 2020 13:26:19
User entered 'AE, right arm erythema and induration' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Oct 2020 13:26:19
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 14:50:44
User opened query 'Per CDM: As per the CCG page 27, please specify the reason for physician decision. Thank you.' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 07:01:25
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 19:47:17

US3672163
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:21:33
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User entered empty.	System	14 Sep 2020 19:47:17

US3672163
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:21:33
What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:59:57
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 14:50:44
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 19:47:17

US3672163
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:21:33
What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:57
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 14:50:44
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 19:47:17

US3672163
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:21:33
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User entered empty.	System	14 Sep 2020 19:47:17

FDA-CBER-2022-1614-2937153

US3672163
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:21:33
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:57
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 14:50:44
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 19:47:17

US3672163
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:21:33
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 14:50:44
User entered empty.	System	14 Sep 2020 19:47:17

US3672163
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:21:33
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User entered empty.	System	14 Sep 2020 19:47:17

US3672163
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:21:33
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:57
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 14:51:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 19:42:53

FDA-CBER-2022-1614-2937157

US3672163
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:21:33
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User closed query 'The Collection Date is greater than the Date of study discontinuation/completion. Please review and reconcile.' (Site from System).	System	08 Apr 2021 17:53:29
User opened query 'The Collection Date is greater than the Date of study discontinuation/completion. Please review and reconcile.' (Site from System).	System	01 Apr 2021 14:30:26
Data hard unlocked.	System	01 Apr 2021 14:30:26
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:57
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 14:51:01
User entered '14 Sep 2020'	(b) (4), (b) (6)	14 Sep 2020 19:42:53

US3672163
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:21:33
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:59:57
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 14:51:01
User entered '15:30'	(b) (4), (b) (6)	14 Sep 2020 19:42:53

US3672163
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:21:33
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User entered '14 Sep 2020 15:30'	System	14 Sep 2020 19:42:53

US3672163
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab
Generated On: 10 Jun 2021 09:21:33
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User closed query 'Collection Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	08 Apr 2021 17:53:29
User opened query 'Collection Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	01 Apr 2021 14:30:26
Data hard unlocked.	System	01 Apr 2021 14:30:26
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:57
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 14:53:30
User entered '14 Sep 2020'	(b) (4), (b) (6)	14 Sep 2020 20:02:01

US3672163
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 09:21:33
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	14 Sep 2020 20:02:01

US3672163
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 09:21:33
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:57
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 14:53:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 20:02:01

US3672163
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 09:21:33
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:59:57
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:35:47
User closed query 'Per source, collection time is 15:41. Please verify and update. Thanks!' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 15:35:45
Query 'Per source, collection time is 15:41. Please verify and update. Thanks!' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	23 Sep 2020 17:49:51
User closed query "Was the sample collected?' is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).	System	23 Sep 2020 17:49:44
Query "Was the sample collected?' is Yes, however, Collection Time is missing. Please review and reconcile.' answered by data change (Site from System).	System	23 Sep 2020 17:49:44
DataPoint Un-verified.	(b) (4), (b) (6)	23 Sep 2020 17:49:44
User entered '15:41' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Sep 2020 17:49:44
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 14:53:30
User opened query 'Per source, collection time is 15:41. Please verify and update. Thanks!' (Site from CRA).	(b) (4), (b) (6)	23 Sep 2020 14:53:23
User opened query "Was the sample collected?' is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).	System	14 Sep 2020 20:02:01
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 20:02:01

US3672163
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 09:21:33
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User entered '14 Sep 2020 15:41'	System	23 Sep 2020 17:49:44
User entered empty.	System	14 Sep 2020 20:02:01

US3672163
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 09:21:33
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	14 Sep 2020 20:02:01

US3672163
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 09:21:33
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:57
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 14:53:30
User entered 'No (N)'	(b) (4), (b) (6)	14 Sep 2020 20:02:01

US3672163
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 09:21:33
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:59:57
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 14:53:30
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 20:02:01

US3672163
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 09:21:33
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User entered empty.	System	14 Sep 2020 20:02:01

US3672163
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:21:33
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:57
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 14:53:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 19:43:00

US3672163
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:21:33
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User entered '1'	System	14 Sep 2020 19:43:00

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US3672163
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:21:33
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 19:23:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 14:00:14

US3672163
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:21:33
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User closed query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	08 Apr 2021 17:53:29
User opened query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	01 Apr 2021 14:30:26
Data hard unlocked.	System	01 Apr 2021 14:30:26
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 19:23:17
User entered '22 Sep 2020'	(b) (4), (b) (6)	22 Sep 2020 14:00:14

US3672163
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:21:33
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 19:23:17
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	22 Sep 2020 14:00:14

US3672163
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:21:33
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 19:23:17
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 14:00:14

US3672163
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:21:33
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 19:23:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 14:00:18

US3672163
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:21:33
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User entered '1'	System	22 Sep 2020 14:00:18

US3672163
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:21:33
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	19 Oct 2020 15:59:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Oct 2020 17:33:58

US3672163
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:21:33
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User closed query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	08 Apr 2021 17:53:29
User opened query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	01 Apr 2021 14:30:26
Data hard unlocked.	System	01 Apr 2021 14:30:26
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	19 Oct 2020 15:59:41
User entered '1 Oct 2020'	(b) (4), (b) (6)	05 Oct 2020 17:33:58

US3672163
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:21:33
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 15:59:41
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	05 Oct 2020 17:33:58

US3672163
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:21:33
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	19 Oct 2020 15:59:41
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 17:33:58

US3672163
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:21:33
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	19 Oct 2020 15:59:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Oct 2020 17:34:01

US3672163
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:21:33
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User entered '1'	System	05 Oct 2020 17:34:01

US3672163
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:21:33
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	19 Oct 2020 16:00:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Oct 2020 17:34:11

US3672163
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:21:33
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User closed query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	08 Apr 2021 17:53:29
User opened query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	01 Apr 2021 14:30:26
Data hard unlocked.	System	01 Apr 2021 14:30:26
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	19 Oct 2020 16:00:25
User entered '5 Oct 2020'	(b) (4), (b) (6)	05 Oct 2020 17:34:11

US3672163
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:21:33
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:00:25
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	05 Oct 2020 17:34:11

FDA-CBER-2022-1614-2937186

US3672163
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:21:33
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	19 Oct 2020 16:00:25
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 17:34:11

US3672163
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:21:33
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:54
DataPoint Verified.	(b) (4), (b) (6)	19 Oct 2020 16:00:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Oct 2020 17:34:14

US3672163
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:21:33
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User entered '1'	System	05 Oct 2020 17:34:14

US3672163
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:21:33
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:57
DataPoint Verified.	(b) (4), (b) (6)	19 Oct 2020 16:02:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 13:14:50

US3672163
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:21:33
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User closed query 'Visit Date is after Date of study discontinuation/completion. Please reconcile.' (Site from System).	System	08 Apr 2021 17:53:29
User opened query 'Visit Date is after Date of study discontinuation/completion. Please reconcile.' (Site from System).	System	01 Apr 2021 14:30:26
Data hard unlocked.	System	01 Apr 2021 14:30:26
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:57
DataPoint Verified.	(b) (4), (b) (6)	19 Oct 2020 16:02:04
User entered '12 Oct 2020'	(b) (4), (b) (6)	12 Oct 2020 13:14:50

FDA-CBER-2022-1614-2937191

US3672163
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:21:33
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:57
DataPoint Verified.	(b) (4), (b) (6)	19 Oct 2020 16:02:04
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	12 Oct 2020 13:14:50

US3672163
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:21:33
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User entered 'VISIT3'	System	12 Oct 2020 13:14:50

FDA-CBER-2022-1614-2937193

US3672163
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:21:33
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:57
DataPoint Verified.	(b) (4), (b) (6)	19 Oct 2020 16:02:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 13:16:38

FDA-CBER-2022-1614-2937194

US3672163
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:21:33
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User closed query 'Date of Assessment is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	08 Apr 2021 17:53:29
User opened query 'Date of Assessment is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	01 Apr 2021 14:30:26
Data hard unlocked.	System	01 Apr 2021 14:30:26
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:57
DataPoint Verified.	(b) (4), (b) (6)	19 Oct 2020 16:02:19
User entered '12 Oct 2020'	(b) (4), (b) (6)	12 Oct 2020 13:16:38

US3672163
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:21:33
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:57
DataPoint Verified.	(b) (4), (b) (6)	19 Oct 2020 16:02:19
User entered '09:05'	(b) (4), (b) (6)	12 Oct 2020 13:16:38

US3672163
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:21:33
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User entered '12 Oct 2020 09:05'	System	12 Oct 2020 13:16:38

FDA-CBER-2022-1614-2937197

US3672163
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:21:33
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:57
DataPoint Verified.	(b) (4), (b) (6)	19 Oct 2020 16:02:19
User entered '98.5' F	(b) (4), (b) (6)	12 Oct 2020 13:16:38

US3672163
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:21:33
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:57
DataPoint Verified.	(b) (4), (b) (6)	19 Oct 2020 16:02:19
User entered 'Oral (Oral)'	(b) (4), (b) (6)	12 Oct 2020 13:16:38

US3672163
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:21:33
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:57
DataPoint Verified.	(b) (4), (b) (6)	19 Oct 2020 16:02:19
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 13:16:38

US3672163
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:21:33
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:57
DataPoint Verified.	(b) (4), (b) (6)	19 Oct 2020 16:02:19
User entered '59'	(b) (4), (b) (6)	12 Oct 2020 13:16:38

US3672163
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:21:33
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User entered 'bpm'	System	12 Oct 2020 13:16:38

FDA-CBER-2022-1614-2937202

US3672163
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:21:33
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:57
DataPoint Verified.	(b) (4), (b) (6)	19 Oct 2020 16:02:19
User entered '14'	(b) (4), (b) (6)	12 Oct 2020 13:16:38

US3672163
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:21:33
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User entered 'breaths/min'	System	12 Oct 2020 13:16:38

FDA-CBER-2022-1614-2937204

US3672163
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:21:33
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:57
DataPoint Verified.	(b) (4), (b) (6)	19 Oct 2020 16:02:19
User entered '133'	(b) (4), (b) (6)	12 Oct 2020 13:16:38

US3672163
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:21:33
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User entered 'mmHg'	System	12 Oct 2020 13:16:38

FDA-CBER-2022-1614-2937206

US3672163
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:21:33
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:57
DataPoint Verified.	(b) (4), (b) (6)	19 Oct 2020 16:02:19
User entered '91'	(b) (4), (b) (6)	12 Oct 2020 13:16:38

US3672163
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:21:33
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User entered 'mmHg'	System	12 Oct 2020 13:16:38

FDA-CBER-2022-1614-2937208

US3672163
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:21:33
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49

FDA-CBER-2022-1614-2937209

US3672163
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:21:33
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49

FDA-CBER-2022-1614-2937210

US3672163
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Generated On: 10 Jun 2021 09:21:33
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 19:59:57
DataPoint Verified.	(b) (4), (b) (6)	19 Oct 2020 16:02:26
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Oct 2020 13:17:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 13:16:49

US3672163
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Generated On: 10 Jun 2021 09:21:33
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:57
DataPoint Verified.	(b) (4), (b) (6)	19 Oct 2020 16:02:26
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	12 Oct 2020 13:17:03
User entered '12 Oct 2020'	(b) (4), (b) (6)	12 Oct 2020 13:16:49

FDA-CBER-2022-1614-2937212

US3672163
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:21:33
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:57
DataPoint Verified.	(b) (4), (b) (6)	19 Oct 2020 16:02:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 13:25:21

US3672163
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:21:33
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User closed query 'The Collection Date is greater than the Date of study discontinuation/completion. Please review and reconcile.' (Site from System).	System	08 Apr 2021 17:53:29
User opened query 'The Collection Date is greater than the Date of study discontinuation/completion. Please review and reconcile.' (Site from System).	System	01 Apr 2021 14:30:26
Data hard unlocked.	System	01 Apr 2021 14:30:26
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:57
DataPoint Verified.	(b) (4), (b) (6)	19 Oct 2020 16:02:52
User entered '12 Oct 2020'	(b) (4), (b) (6)	12 Oct 2020 13:25:21

US3672163
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:21:33
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:57
DataPoint Verified.	(b) (4), (b) (6)	19 Oct 2020 16:02:52
User entered '09:19'	(b) (4), (b) (6)	12 Oct 2020 13:25:21

US3672163
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:21:33
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User entered '12 Oct 2020 09:19'	System	12 Oct 2020 13:25:21

FDA-CBER-2022-1614-2937216

US3672163
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:21:33
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 19:59:57
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 18:24:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 13:25:26

FDA-CBER-2022-1614-2937217

US3672163
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:21:33
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User entered '1'	System	12 Oct 2020 13:25:26

US3672163
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
Data entry locked.	System	18 Aug 2020 17:59:45
User entered 'Day 64'	System	18 Aug 2020 17:59:45

FDA-CBER-2022-1614-2937219

US3672163

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:33

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-10-21T19:04:33', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '0b43de2f-d087-44cc-9c8f-1e1a2a6d9f13'	System	21 Oct 2020 23:04:50
User entered 'No (N)'	System	21 Oct 2020 23:04:50

US3672163

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:33

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-10-21T19:04:41', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '0b43de2f-d087-44cc-9c8f-1e1a2a6d9f13'	System	21 Oct 2020 23:04:50
User entered 'No (N)'	System	21 Oct 2020 23:04:50

US3672163
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-10-21T19:04:47', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '0b43de2f-d087-44cc-9c8f-1e1a2a6d9f13'	System	21 Oct 2020 23:04:50
User entered '21 Oct 2020 19:04:47'	System	21 Oct 2020 23:04:50

US3672163
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
Data entry locked.	System	18 Aug 2020 17:59:45
User entered '18 Oct 2020 00:01'	System	18 Aug 2020 17:59:45

US3672163
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
Data entry locked.	System	18 Aug 2020 17:59:45
User entered '22 Oct 2020 23:59'	System	18 Aug 2020 17:59:45

US3672163
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
Data entry locked.	System	18 Aug 2020 17:59:45
User entered 'Day 71'	System	18 Aug 2020 17:59:45

FDA-CBER-2022-1614-2937225

US3672163

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:33

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-10-25T08:28:25', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '25882033-2289-454f-b953-063edb83d8db'	System	25 Oct 2020 12:28:43
User entered 'No (N)'	System	25 Oct 2020 12:28:43

US3672163

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:33

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-10-25T08:28:32', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '25882033-2289-454f-b953-063edb83d8db'	System	25 Oct 2020 12:28:43
User entered 'No (N)'	System	25 Oct 2020 12:28:43

US3672163
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-10-25T08:28:39', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '25882033-2289-454f-b953-063edb83d8db'	System	25 Oct 2020 12:28:43
User entered '25 Oct 2020 08:28:39'	System	25 Oct 2020 12:28:43

US3672163
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
Data entry locked.	System	18 Aug 2020 17:59:45
User entered '25 Oct 2020 00:01'	System	18 Aug 2020 17:59:45

US3672163
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
Data entry locked.	System	18 Aug 2020 17:59:45
User entered '29 Oct 2020 23:59'	System	18 Aug 2020 17:59:45

US3672163
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
Data entry locked.	System	18 Aug 2020 17:59:45
User entered 'Day 78'	System	18 Aug 2020 17:59:45

US3672163

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:33

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-11-01T09:39:29', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '34278ede-006d-4a90-b3de-7536284d050e'	System	01 Nov 2020 14:39:39
User entered 'No (N)'	System	01 Nov 2020 14:39:39

US3672163

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:33

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-11-01T09:39:32', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '34278ede-006d-4a90-b3de-7536284d050e'	System	01 Nov 2020 14:39:39
User entered 'No (N)'	System	01 Nov 2020 14:39:39

US3672163
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-11-01T09:39:36', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '34278ede-006d-4a90-b3de-7536284d050e'	System	01 Nov 2020 14:39:39
User entered '01 Nov 2020 09:39:36'	System	01 Nov 2020 14:39:39

US3672163
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
Data entry locked.	System	18 Aug 2020 17:59:45
User entered '01 Nov 2020 00:01'	System	18 Aug 2020 17:59:45

US3672163
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
Data entry locked.	System	18 Aug 2020 17:59:45
User entered '05 Nov 2020 23:59'	System	18 Aug 2020 17:59:45

FDA-CBER-2022-1614-2937236

US3672163
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
Data entry locked.	System	18 Aug 2020 17:59:45
User entered 'Day 92'	System	18 Aug 2020 17:59:45

US3672163

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:33

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-11-16T09:08:11', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '0866f08d-1122-42bc-84c0-8c912bc690bf'	System	16 Nov 2020 14:08:23
User entered 'No (N)'	System	16 Nov 2020 14:08:23

US3672163

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:33

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-11-16T09:08:17', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '0866f08d-1122-42bc-84c0-8c912bc690bf'	System	16 Nov 2020 14:08:23
User entered 'No (N)'	System	16 Nov 2020 14:08:23

US3672163
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-11-16T09:08:21', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '0866f08d-1122-42bc-84c0-8c912bc690bf'	System	16 Nov 2020 14:08:23
User entered '16 Nov 2020 09:08:21'	System	16 Nov 2020 14:08:23

US3672163
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
Data entry locked.	System	18 Aug 2020 17:59:45
User entered '15 Nov 2020 00:01'	System	18 Aug 2020 17:59:45

FDA-CBER-2022-1614-2937241

US3672163
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:11:35
Data entry locked.	System	18 Aug 2020 17:59:45
User entered '19 Nov 2020 23:59'	System	18 Aug 2020 17:59:45

FDA-CBER-2022-1614-2937242

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:20:18
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 22:20:18

US3672163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:33

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-11-22T07:23:41', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '5a0e00de-f5de-4f26-aa10-8579812a44d8'	System	22 Nov 2020 12:23:55
User entered 'No (N)'	System	22 Nov 2020 12:23:55

US3672163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:33

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-11-22T07:23:48', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '5a0e00de-f5de-4f26-aa10-8579812a44d8'	System	22 Nov 2020 12:23:55
User entered 'No (N)'	System	22 Nov 2020 12:23:55

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-11-22T07:23:52', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '5a0e00de-f5de-4f26-aa10-8579812a44d8'	System	22 Nov 2020 12:23:55
User entered '22 Nov 2020 07:23:52'	System	22 Nov 2020 12:23:55

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:20:18
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 22:20:18

FDA-CBER-2022-1614-2937247

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:20:18
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 22:20:18

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:20:18
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 22:20:18

US3672163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:33

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-11-30T08:30:18', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '55f4e97a-55e7-4654-9ad3-5885ff674c21'	System	30 Nov 2020 13:30:41
User entered 'No (N)'	System	30 Nov 2020 13:30:41

US3672163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:33

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-11-30T08:30:34', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '55f4e97a-55e7-4654-9ad3-5885ff674c21'	System	30 Nov 2020 13:30:41
User entered 'No (N)'	System	30 Nov 2020 13:30:41

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-11-30T08:30:37', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '55f4e97a-55e7-4654-9ad3-5885ff674c21'	System	30 Nov 2020 13:30:41
User entered '30 Nov 2020 08:30:37'	System	30 Nov 2020 13:30:41

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:20:18
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 22:20:18

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:20:18
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 22:20:18

FDA-CBER-2022-1614-2937254

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:20:18
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 22:20:18

US3672163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:33

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-12-05T19:28:06', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: 'd268e02c-953f-4ed8-87cd-e57dd0906628'	System	06 Dec 2020 00:28:17
User entered 'No (N)'	System	06 Dec 2020 00:28:17

US3672163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:33

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-12-05T19:28:12', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: 'd268e02c-953f-4ed8-87cd-e57dd0906628'	System	06 Dec 2020 00:28:17
User entered 'No (N)'	System	06 Dec 2020 00:28:17

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-12-05T19:28:15', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: 'd268e02c-953f-4ed8-87cd-e57dd0906628'	System	06 Dec 2020 00:28:17
User entered '05 Dec 2020 19:28:15'	System	06 Dec 2020 00:28:17

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:20:18
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 22:20:18

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:20:18
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 22:20:18

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:20:18
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 22:20:18

US3672163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:33

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-12-10T07:47:36', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: 'd392ffea-a122-4b48-98e4-738d95ffeb2e'	System	10 Dec 2020 12:47:48
User entered 'No (N)'	System	10 Dec 2020 12:47:48

US3672163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:33

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-12-10T07:47:43', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: 'd392ffea-a122-4b48-98e4-738d95ffeb2e'	System	10 Dec 2020 12:47:48
User entered 'No (N)'	System	10 Dec 2020 12:47:48

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-12-10T07:47:46', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: 'd392ffea-a122-4b48-98e4-738d95ffeb2e'	System	10 Dec 2020 12:47:48
User entered '10 Dec 2020 07:47:46'	System	10 Dec 2020 12:47:48

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:20:18
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 22:20:18

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:20:18
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 22:20:18

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
DataPoint Activated.	System	08 Apr 2021 17:53:29
DataPoint Inactivated.	System	01 Apr 2021 14:30:26
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:20:18
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 22:20:18

US3672163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:33

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
DataPoint Activated.	System	08 Apr 2021 17:53:29
DataPoint Inactivated.	System	01 Apr 2021 14:30:26

US3672163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:33

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
DataPoint Activated.	System	08 Apr 2021 17:53:29
DataPoint Inactivated.	System	01 Apr 2021 14:30:26

US3672163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
DataPoint Activated.	System	08 Apr 2021 17:53:29
DataPoint Inactivated.	System	01 Apr 2021 14:30:26

US3672163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:33

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
DataPoint Activated.	System	08 Apr 2021 17:53:29
DataPoint Inactivated.	System	01 Apr 2021 14:30:26

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
DataPoint Activated.	System	08 Apr 2021 17:53:29
DataPoint Inactivated.	System	01 Apr 2021 14:30:26

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
DataPoint Activated.	System	08 Apr 2021 17:53:29
DataPoint Inactivated.	System	01 Apr 2021 14:30:26

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
DataPoint Activated.	System	08 Apr 2021 17:53:29
DataPoint Inactivated.	System	01 Apr 2021 14:30:26

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
DataPoint Activated.	System	08 Apr 2021 17:53:29
DataPoint Inactivated.	System	01 Apr 2021 14:30:26

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
DataPoint Activated.	System	08 Apr 2021 17:53:29
DataPoint Inactivated.	System	01 Apr 2021 14:30:26

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
DataPoint Activated.	System	08 Apr 2021 17:53:29
DataPoint Inactivated.	System	01 Apr 2021 14:30:26

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
DataPoint Activated.	System	08 Apr 2021 17:53:29
DataPoint Inactivated.	System	01 Apr 2021 14:30:26

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
DataPoint Activated.	System	08 Apr 2021 17:53:29
DataPoint Inactivated.	System	01 Apr 2021 14:30:26

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
DataPoint Activated.	System	08 Apr 2021 17:53:29
DataPoint Inactivated.	System	01 Apr 2021 14:30:26

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
DataPoint Activated.	System	08 Apr 2021 17:53:29
DataPoint Inactivated.	System	01 Apr 2021 14:30:26

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
DataPoint Activated.	System	08 Apr 2021 17:53:29
DataPoint Inactivated.	System	01 Apr 2021 14:30:26

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
DataPoint Activated.	System	08 Apr 2021 17:53:29
DataPoint Inactivated.	System	01 Apr 2021 14:30:26

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
DataPoint Activated.	System	08 Apr 2021 17:53:29
DataPoint Inactivated.	System	01 Apr 2021 14:30:26

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
DataPoint Activated.	System	08 Apr 2021 17:53:29
DataPoint Inactivated.	System	01 Apr 2021 14:30:26

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
DataPoint Activated.	System	08 Apr 2021 17:53:29
DataPoint Inactivated.	System	01 Apr 2021 14:30:26

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
DataPoint Activated.	System	08 Apr 2021 17:53:29
DataPoint Inactivated.	System	01 Apr 2021 14:30:26

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
DataPoint Activated.	System	08 Apr 2021 17:53:29
DataPoint Inactivated.	System	01 Apr 2021 14:30:26

US3672163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
DataPoint Activated.	System	08 Apr 2021 17:53:29
DataPoint Inactivated.	System	01 Apr 2021 14:30:26

US3672163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:33

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
DataPoint Activated.	System	08 Apr 2021 17:53:29
DataPoint Inactivated.	System	01 Apr 2021 14:30:26

US3672163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
DataPoint Activated.	System	08 Apr 2021 17:53:29
DataPoint Inactivated.	System	01 Apr 2021 14:30:26

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
DataPoint Activated.	System	08 Apr 2021 17:53:29
DataPoint Inactivated.	System	01 Apr 2021 14:30:26

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
DataPoint Activated.	System	08 Apr 2021 17:53:29
DataPoint Inactivated.	System	01 Apr 2021 14:30:26
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:20:18
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 22:20:18

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
DataPoint Activated.	System	08 Apr 2021 17:53:29
DataPoint Inactivated.	System	01 Apr 2021 14:30:26
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:20:18
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 22:20:18

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:20:18
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 22:20:18

US3672163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:33

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-12-26T12:01:03', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '4fb3cf89-20cb-4126-934f-8039421145ba'	System	26 Dec 2020 17:01:25
User entered 'No (N)'	System	26 Dec 2020 17:01:25

US3672163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:33

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-12-26T12:01:09', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '4fb3cf89-20cb-4126-934f-8039421145ba'	System	26 Dec 2020 17:01:25
User entered 'No (N)'	System	26 Dec 2020 17:01:25

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2020-12-26T12:01:13', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '4fb3cf89-20cb-4126-934f-8039421145ba'	System	26 Dec 2020 17:01:25
User entered '26 Dec 2020 12:01:13'	System	26 Dec 2020 17:01:25

FDA-CBER-2022-1614-2937298

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:20:18
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 22:20:18

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:20:18
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 22:20:18

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:20:18
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 22:20:18

US3672163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:33

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2021-01-02T17:30:06', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: 'e9b2ca4b-73ba-4c69-8e54-5d258dbf611a'	System	02 Jan 2021 22:30:16
User entered 'No (N)'	System	02 Jan 2021 22:30:16

US3672163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:33

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2021-01-02T17:30:09', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: 'e9b2ca4b-73ba-4c69-8e54-5d258dbf611a'	System	02 Jan 2021 22:30:16
User entered 'No (N)'	System	02 Jan 2021 22:30:16

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2021-01-02T17:30:12', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: 'e9b2ca4b-73ba-4c69-8e54-5d258dbf611a'	System	02 Jan 2021 22:30:16
User entered '02 Jan 2021 17:30:12'	System	02 Jan 2021 22:30:16

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:20:18
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 22:20:18

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:20:18
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 22:20:18

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:20:18
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 22:20:18

US3672163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:33

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2021-01-08T07:30:31', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '38d36c0b-ace7-492f-8993-abe3660e472e'	System	08 Jan 2021 12:30:46
User entered 'No (N)'	System	08 Jan 2021 12:30:46

US3672163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:33

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2021-01-08T07:30:35', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '38d36c0b-ace7-492f-8993-abe3660e472e'	System	08 Jan 2021 12:30:46
User entered 'No (N)'	System	08 Jan 2021 12:30:46

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2021-01-08T07:30:41', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '38d36c0b-ace7-492f-8993-abe3660e472e'	System	08 Jan 2021 12:30:46
User entered '08 Jan 2021 07:30:41'	System	08 Jan 2021 12:30:46

FDA-CBER-2022-1614-2937310

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:20:18
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 22:20:18

FDA-CBER-2022-1614-2937311

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:20:18
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 22:20:18

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:20:18
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 22:20:18

US3672163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:33

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2021-01-14T11:07:53', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '3abae07f-1b3f-4e2c-a60b-91053e0c7ee9'	System	14 Jan 2021 16:08:24
User entered 'No (N)'	System	14 Jan 2021 16:08:24

US3672163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:33

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2021-01-14T11:07:58', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '3abae07f-1b3f-4e2c-a60b-91053e0c7ee9'	System	14 Jan 2021 16:08:24
User entered 'Yes (Y)'	System	14 Jan 2021 16:08:24

US3672163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2021-01-14T11:08:08', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '3abae07f-1b3f-4e2c-a60b-91053e0c7ee9'	System	14 Jan 2021 16:08:24
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	14 Jan 2021 16:08:24

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2021-01-14T11:08:15', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '3abae07f-1b3f-4e2c-a60b-91053e0c7ee9'	System	14 Jan 2021 16:08:24
User entered '14 Jan 2021 11:08:15'	System	14 Jan 2021 16:08:24

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:20:18
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 22:20:18

FDA-CBER-2022-1614-2937318

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:20:18
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 22:20:18

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:20:18
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 22:20:18

US3672163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:33

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2021-01-25T11:59:28', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: 'a2652e7e-dfe2-4b05-9551-6836eeb0c1a2'	System	25 Jan 2021 16:59:37
User entered 'No (N)'	System	25 Jan 2021 16:59:37

US3672163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:33

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2021-01-25T11:59:31', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: 'a2652e7e-dfe2-4b05-9551-6836eeb0c1a2'	System	25 Jan 2021 16:59:37
User entered 'No (N)'	System	25 Jan 2021 16:59:37

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2021-01-25T11:59:33', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: 'a2652e7e-dfe2-4b05-9551-6836eeb0c1a2'	System	25 Jan 2021 16:59:37
User entered '25 Jan 2021 11:59:33'	System	25 Jan 2021 16:59:37

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:20:18
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 22:20:18

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:20:18
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 22:20:18

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:20:18
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 22:20:18

US3672163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:33

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2021-01-30T12:00:28', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '1aa196b9-fd47-4c7b-adb1-0b494c937760'	System	30 Jan 2021 17:01:41
User entered 'No (N)'	System	30 Jan 2021 17:01:41

US3672163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:33

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2021-01-30T12:00:33', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '1aa196b9-fd47-4c7b-adb1-0b494c937760'	System	30 Jan 2021 17:01:41
User entered 'No (N)'	System	30 Jan 2021 17:01:41

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2021-01-30T12:00:36', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '1aa196b9-fd47-4c7b-adb1-0b494c937760'	System	30 Jan 2021 17:01:41
User entered '30 Jan 2021 12:00:36'	System	30 Jan 2021 17:01:41

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:20:18
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 22:20:18

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:20:18
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 22:20:18

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
DataPoint Activated.	System	08 Apr 2021 17:53:29
DataPoint Inactivated.	System	01 Apr 2021 14:30:26
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:20:18
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 22:20:18

US3672163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:33

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
DataPoint Activated.	System	08 Apr 2021 17:53:29
DataPoint Inactivated.	System	01 Apr 2021 14:30:26

US3672163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:33

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
DataPoint Activated.	System	08 Apr 2021 17:53:29
DataPoint Inactivated.	System	01 Apr 2021 14:30:26

US3672163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
DataPoint Activated.	System	08 Apr 2021 17:53:29
DataPoint Inactivated.	System	01 Apr 2021 14:30:26

US3672163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:33

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
DataPoint Activated.	System	08 Apr 2021 17:53:29
DataPoint Inactivated.	System	01 Apr 2021 14:30:26

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
DataPoint Activated.	System	08 Apr 2021 17:53:29
DataPoint Inactivated.	System	01 Apr 2021 14:30:26

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
DataPoint Activated.	System	08 Apr 2021 17:53:29
DataPoint Inactivated.	System	01 Apr 2021 14:30:26

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
DataPoint Activated.	System	08 Apr 2021 17:53:29
DataPoint Inactivated.	System	01 Apr 2021 14:30:26

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
DataPoint Activated.	System	08 Apr 2021 17:53:29
DataPoint Inactivated.	System	01 Apr 2021 14:30:26

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
DataPoint Activated.	System	08 Apr 2021 17:53:29
DataPoint Inactivated.	System	01 Apr 2021 14:30:26

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
DataPoint Activated.	System	08 Apr 2021 17:53:29
DataPoint Inactivated.	System	01 Apr 2021 14:30:26

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
DataPoint Activated.	System	08 Apr 2021 17:53:29
DataPoint Inactivated.	System	01 Apr 2021 14:30:26

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
DataPoint Activated.	System	08 Apr 2021 17:53:29
DataPoint Inactivated.	System	01 Apr 2021 14:30:26

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
DataPoint Activated.	System	08 Apr 2021 17:53:29
DataPoint Inactivated.	System	01 Apr 2021 14:30:26

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
DataPoint Activated.	System	08 Apr 2021 17:53:29
DataPoint Inactivated.	System	01 Apr 2021 14:30:26

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
DataPoint Activated.	System	08 Apr 2021 17:53:29
DataPoint Inactivated.	System	01 Apr 2021 14:30:26

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
DataPoint Activated.	System	08 Apr 2021 17:53:29
DataPoint Inactivated.	System	01 Apr 2021 14:30:26

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
DataPoint Activated.	System	08 Apr 2021 17:53:29
DataPoint Inactivated.	System	01 Apr 2021 14:30:26

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
DataPoint Activated.	System	08 Apr 2021 17:53:29
DataPoint Inactivated.	System	01 Apr 2021 14:30:26

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
DataPoint Activated.	System	08 Apr 2021 17:53:29
DataPoint Inactivated.	System	01 Apr 2021 14:30:26

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
DataPoint Activated.	System	08 Apr 2021 17:53:29
DataPoint Inactivated.	System	01 Apr 2021 14:30:26

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
DataPoint Activated.	System	08 Apr 2021 17:53:29
DataPoint Inactivated.	System	01 Apr 2021 14:30:26

US3672163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
DataPoint Activated.	System	08 Apr 2021 17:53:29
DataPoint Inactivated.	System	01 Apr 2021 14:30:26

US3672163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:33

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
DataPoint Activated.	System	08 Apr 2021 17:53:29
DataPoint Inactivated.	System	01 Apr 2021 14:30:26

US3672163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
DataPoint Activated.	System	08 Apr 2021 17:53:29
DataPoint Inactivated.	System	01 Apr 2021 14:30:26

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
DataPoint Activated.	System	08 Apr 2021 17:53:29
DataPoint Inactivated.	System	01 Apr 2021 14:30:26

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
DataPoint Activated.	System	08 Apr 2021 17:53:29
DataPoint Inactivated.	System	01 Apr 2021 14:30:26
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:20:18
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 22:20:18

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
DataPoint Activated.	System	08 Apr 2021 17:53:29
DataPoint Inactivated.	System	01 Apr 2021 14:30:26
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:20:18
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 22:20:18

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:20:18
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 22:20:18

US3672163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:33

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2021-02-13T12:00:29', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '160e177c-970e-4638-b4c1-6d8498c3c15c'	System	13 Feb 2021 17:02:30
User entered 'No (N)'	System	13 Feb 2021 17:02:30

US3672163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:33

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2021-02-13T12:00:31', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '160e177c-970e-4638-b4c1-6d8498c3c15c'	System	13 Feb 2021 17:02:30
User entered 'No (N)'	System	13 Feb 2021 17:02:30

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2021-02-13T12:00:34', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '160e177c-970e-4638-b4c1-6d8498c3c15c'	System	13 Feb 2021 17:02:30
User entered '13 Feb 2021 12:00:34'	System	13 Feb 2021 17:02:30

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:20:18
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 22:20:18

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:20:18
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 22:20:18

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:20:18
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 22:20:18

US3672163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:33

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2021-02-19T08:33:10', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '660cb9b2-74bd-4ea0-9be9-165afb6e4e55'	System	19 Feb 2021 13:33:41
User entered 'No (N)'	System	19 Feb 2021 13:33:41

US3672163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:33

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2021-02-19T08:33:26', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '660cb9b2-74bd-4ea0-9be9-165afb6e4e55'	System	19 Feb 2021 13:33:41
User entered 'No (N)'	System	19 Feb 2021 13:33:41

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2021-02-19T08:33:36', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '660cb9b2-74bd-4ea0-9be9-165afb6e4e55'	System	19 Feb 2021 13:33:41
User entered '19 Feb 2021 08:33:36'	System	19 Feb 2021 13:33:41

FDA-CBER-2022-1614-2937369

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:20:18
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 22:20:18

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:20:18
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 22:20:18

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:20:18
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 22:20:18

US3672163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:33

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2021-03-01T06:56:15-05:00', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '68ff7d39-b3e6-4c39-a886-c731e2b7e0d2'	System	01 Mar 2021 11:56:24
User entered 'No (N)'	System	01 Mar 2021 11:56:24

US3672163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:33

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2021-03-01T06:56:17-05:00', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '68ff7d39-b3e6-4c39-a886-c731e2b7e0d2'	System	01 Mar 2021 11:56:24
User entered 'No (N)'	System	01 Mar 2021 11:56:24

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2021-03-01T06:56:21-05:00', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '68ff7d39-b3e6-4c39-a886-c731e2b7e0d2'	System	01 Mar 2021 11:56:24
User entered '01 Mar 2021 11:56:21'	System	01 Mar 2021 11:56:24

FDA-CBER-2022-1614-2937375

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:20:18
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 22:20:18

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:20:18
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 22:20:18

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:20:18
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 22:20:18

US3672163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:33

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2021-03-06T21:44:13-05:00', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '916ae37b-54e3-4549-a486-31f2fbeaf387'	System	07 Mar 2021 02:44:27
User entered 'No (N)'	System	07 Mar 2021 02:44:27

US3672163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:33

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2021-03-06T21:44:16-05:00', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '916ae37b-54e3-4549-a486-31f2fbeaf387'	System	07 Mar 2021 02:44:27
User entered 'No (N)'	System	07 Mar 2021 02:44:27

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2021-03-06T21:44:20-05:00', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '916ae37b-54e3-4549-a486-31f2fbeaf387'	System	07 Mar 2021 02:44:27
User entered '06 Mar 2021 21:44:20'	System	07 Mar 2021 02:44:27

FDA-CBER-2022-1614-2937381

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:20:18
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 22:20:18

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:20:18
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 22:20:18

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:20:18
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 22:20:18

US3672163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:33

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2021-03-15T09:33:13-04:00', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: 'b52b3121-7410-425f-8325-6f91392b3d8a'	System	15 Mar 2021 13:33:23
User entered 'No (N)'	System	15 Mar 2021 13:33:23

US3672163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:33

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2021-03-15T09:33:15-04:00', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: 'b52b3121-7410-425f-8325-6f91392b3d8a'	System	15 Mar 2021 13:33:23
User entered 'No (N)'	System	15 Mar 2021 13:33:23

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2021-03-15T09:33:19-04:00', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: 'b52b3121-7410-425f-8325-6f91392b3d8a'	System	15 Mar 2021 13:33:23
User entered '15 Mar 2021 09:33:19'	System	15 Mar 2021 13:33:23

FDA-CBER-2022-1614-2937387

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:20:18
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 22:20:18

FDA-CBER-2022-1614-2937388

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:20:18
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 22:20:18

FDA-CBER-2022-1614-2937389

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:20:18
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 22:20:18

US3672163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:33

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2021-03-18T07:36:33-04:00', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: 'ee73caab-620a-42e8-b44c-04fe407cb546'	System	18 Mar 2021 11:36:44
User entered 'No (N)'	System	18 Mar 2021 11:36:44

US3672163

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:21:33

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2021-03-18T07:36:36-04:00', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: 'ee73caab-620a-42e8-b44c-04fe407cb546'	System	18 Mar 2021 11:36:44
User entered 'No (N)'	System	18 Mar 2021 11:36:44

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2021-03-18T07:36:39-04:00', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: 'ee73caab-620a-42e8-b44c-04fe407cb546'	System	18 Mar 2021 11:36:44
User entered '18 Mar 2021 07:36:39'	System	18 Mar 2021 11:36:44

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:20:18
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 22:20:18

US3672163
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:21:33
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:20:18
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 22:20:18

US3672163

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:21:33

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2021-03-01T06:56:28-05:00', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '464b71c4-70b0-4f3e-9271-3104d5569a5d'	System	01 Mar 2021 11:56:35
User entered 'No (N)'	System	01 Mar 2021 11:56:35

US3672163
Folder: Cosmetic Injections and Dermal Fillers
Form: Cosmetic Injection_ Dermal Filler eDiary (1)
Generated On: 10 Jun 2021 09:21:33
Date & Time of Submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB7DA7B6-CDAD-4F41-99DA-95CA46CF3F60)', Time: '2021-03-01T06:56:32-05:00', User OID: 'PatientReportedOutcome (US3672163)', ODM File OID: '464b71c4-70b0-4f3e-9271-3104d5569a5d'	System	01 Mar 2021 11:56:35
User entered '01 Mar 2021 11:56:32'	System	01 Mar 2021 11:56:35

US3672163
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:21:33
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 18:21:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Dec 2020 11:28:10

US3672163
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:21:33
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User closed query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	08 Apr 2021 17:53:29
User opened query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	01 Apr 2021 14:30:26
Data hard unlocked.	System	01 Apr 2021 14:30:26
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 18:21:29
User entered '9 Nov 2020'	(b) (4), (b) (6)	11 Dec 2020 11:28:10

US3672163
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:21:33
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 18:21:29
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	11 Dec 2020 11:28:10

US3672163
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:21:33
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 18:21:29
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 11:28:10

FDA-CBER-2022-1614-2937401

US3672163
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:21:33
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 18:21:33
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Dec 2020 11:28:14

FDA-CBER-2022-1614-2937402

US3672163
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:21:33
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:56:49
User entered '1'	System	11 Dec 2020 11:28:14

US3672163
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:21:33
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 18:27:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Dec 2020 11:28:23

US3672163
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:21:33
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User closed query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	08 Apr 2021 17:53:29
User opened query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	01 Apr 2021 14:30:26
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 18:27:19
User entered '10 Dec 2020'	(b) (4), (b) (6)	11 Dec 2020 11:28:23

FDA-CBER-2022-1614-2937405

US3672163
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:21:33
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 18:27:19
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	11 Dec 2020 11:28:23

US3672163
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:21:33
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 18:27:19
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 11:28:23

FDA-CBER-2022-1614-2937407

US3672163
Folder: Safety Call Day 119 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:21:33
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 18:27:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Dec 2020 11:28:27

US3672163
Folder: Safety Call Day 119 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:21:33
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User entered '1'	System	11 Dec 2020 11:28:27

US3672163
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:21:33
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 18:27:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Jan 2021 15:01:18

US3672163
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:21:33
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User closed query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	08 Apr 2021 17:53:29
User opened query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	01 Apr 2021 14:30:26
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 18:27:27
User entered '12 Jan 2021'	(b) (4), (b) (6)	13 Jan 2021 15:01:18

US3672163
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:21:33
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 18:27:27
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	13 Jan 2021 15:01:18

US3672163
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:21:33
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 18:27:27
User entered empty.	(b) (4), (b) (6)	13 Jan 2021 15:01:18

FDA-CBER-2022-1614-2937413

US3672163
Folder: Safety Call Day 149 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:21:33
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 18:27:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Jan 2021 15:01:23

US3672163
Folder: Safety Call Day 149 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:21:33
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User entered '1'	System	13 Jan 2021 15:01:23

US3672163
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:21:33
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:21:39
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:57:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 17:34:39

US3672163
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:21:33
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User closed query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	08 Apr 2021 17:53:29
User opened query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	01 Apr 2021 14:30:26
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:21:39
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:57:43
User entered '15 Feb 2021'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 17:34:39

FDA-CBER-2022-1614-2937417

US3672163
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:21:33
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:21:39
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:57:43
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 17:34:39

FDA-CBER-2022-1614-2937418

US3672163
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:21:33
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:21:39
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:57:43
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 17:34:39

FDA-CBER-2022-1614-2937419

US3672163
Folder: Safety Call Day 179 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:21:33
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:21:57
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:57:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 17:34:49

US3672163
Folder: Safety Call Day 179 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:21:33
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User entered '1'	System	15 Feb 2021 17:34:49

FDA-CBER-2022-1614-2937421

US3672163
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:21:33
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 17:37:16
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:57:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Mar 2021 21:38:31

FDA-CBER-2022-1614-2937422

US3672163
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:21:33
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User closed query 'Visit Date is after Date of study discontinuation/completion. Please reconcile.' (Site from System).	System	08 Apr 2021 17:53:29
User opened query 'Visit Date is after Date of study discontinuation/completion. Please reconcile.' (Site from System).	System	01 Apr 2021 14:30:26
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 17:37:16
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:57:43
User entered '1 Mar 2021'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 21:38:31

FDA-CBER-2022-1614-2937423

US3672163
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:21:33
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 17:37:16
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:57:43
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 21:38:31

US3672163
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:21:33
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User entered 'VISIT4'	System	01 Mar 2021 21:38:31

FDA-CBER-2022-1614-2937425

US3672163
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:21:33
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	16 Apr 2021 15:06:07
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:38:38
User entered 'No (N)'	(b) (4), (b) (6)	01 Apr 2021 14:24:29

US3672163
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:21:33
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	16 Apr 2021 15:06:07
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:38:38
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 14:24:29

FDA-CBER-2022-1614-2937427

US3672163
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:21:33
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	16 Apr 2021 15:06:07
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:38:38
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 14:24:29

FDA-CBER-2022-1614-2937428

US3672163
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:21:33
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User entered empty.	System	01 Apr 2021 14:24:29

FDA-CBER-2022-1614-2937429

US3672163
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:21:33
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	16 Apr 2021 15:06:07
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:38:38
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 14:24:29

FDA-CBER-2022-1614-2937430

US3672163
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:21:33
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	16 Apr 2021 15:06:07
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:38:38
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 14:24:29

FDA-CBER-2022-1614-2937431

US3672163
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:21:33
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	16 Apr 2021 15:06:07
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:38:38
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 14:24:29

FDA-CBER-2022-1614-2937432

US3672163
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:21:33
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	16 Apr 2021 15:06:07
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:38:38
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 14:24:29

FDA-CBER-2022-1614-2937433

US3672163
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:21:33
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User entered empty.	System	01 Apr 2021 14:24:29

FDA-CBER-2022-1614-2937434

US3672163
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:21:33
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	16 Apr 2021 15:06:07
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:38:38
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 14:24:29

FDA-CBER-2022-1614-2937435

US3672163
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:21:33
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User entered empty.	System	01 Apr 2021 14:24:29

US3672163
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:21:33
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	16 Apr 2021 15:06:07
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:38:38
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 14:24:29

FDA-CBER-2022-1614-2937437

US3672163
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:21:33
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User entered empty.	System	01 Apr 2021 14:24:29

FDA-CBER-2022-1614-2937438

US3672163
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:21:33
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	16 Apr 2021 15:06:07
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 17:38:38
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 14:24:29

FDA-CBER-2022-1614-2937439

US3672163
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:21:33
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User entered empty.	System	01 Apr 2021 14:24:29

US3672163
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:21:33
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27

FDA-CBER-2022-1614-2937441

US3672163
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:21:33
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27

FDA-CBER-2022-1614-2937442

US3672163
Folder: Visit 4 Day 209 (1)
Form: Physical Examination
Generated On: 10 Jun 2021 09:21:33
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 17:38:29
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:57:43
User entered 'No (N)'	(b) (4), (b) (6)	01 Mar 2021 21:38:35

FDA-CBER-2022-1614-2937443

US3672163
Folder: Visit 4 Day 209 (1)
Form: Physical Examination
Generated On: 10 Jun 2021 09:21:33
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 17:38:29
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:57:43
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 21:38:35

FDA-CBER-2022-1614-2937444

US3672163
Folder: Visit 4 Day 209 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:21:33
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 17:38:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:57:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Mar 2021 21:38:44

US3672163
Folder: Visit 4 Day 209 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:21:33
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User closed query 'The Collection Date is greater than the Date of study discontinuation/completion. Please review and reconcile.' (Site from System).	System	08 Apr 2021 17:53:29
User opened query 'The Collection Date is greater than the Date of study discontinuation/completion. Please review and reconcile.' (Site from System).	System	01 Apr 2021 14:30:26
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 17:38:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:57:43
User entered '1 Mar 2021'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 21:38:44

FDA-CBER-2022-1614-2937446

US3672163
Folder: Visit 4 Day 209 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:21:33
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 17:38:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:57:43
User entered '16:20'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 21:38:44

US3672163
Folder: Visit 4 Day 209 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:21:33
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User entered '1 Mar 2021 16:20'	System	01 Mar 2021 21:38:44

FDA-CBER-2022-1614-2937448

US3672163
Folder: Visit 4 Day 209 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:21:33
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User closed query 'please update End of Study tab for withdrawing IC' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 14:57:42
Query 'please update End of Study tab for withdrawing IC' answered with 'COMPLETED' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 22:50:43
User opened query 'please update End of Study tab for withdrawing IC' (Site from CRA).	(b) (4), (b) (6)	23 Mar 2021 17:39:11
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 17:38:36
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:57:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 21:38:49

US3672163
Folder: Visit 4 Day 209 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:21:33
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User entered empty.	System	01 Mar 2021 21:38:49

US3672163
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:21:33
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:22:10
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Jan 2021 16:11:04

US3672163
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:21:33
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User closed query 'Visit Date is after Date of study discontinuation/completion. Please reconcile.' (Site from System).	System	08 Apr 2021 17:53:29
User opened query 'Visit Date is after Date of study discontinuation/completion. Please reconcile.' (Site from System).	System	01 Apr 2021 14:30:26
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:22:10
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
User entered '19 Jan 2021'	(b) (4), (b) (6)	20 Jan 2021 16:11:04

US3672163
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:21:33
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:22:10
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:57:43
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	20 Jan 2021 16:11:04

US3672163
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:21:33
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User entered 'UNBLND_DECIDE'	System	20 Jan 2021 16:11:04

US3672163
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 09:21:33
Date of updated informed consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:22:42
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:57:43
User entered '19 Jan 2021'	(b) (4), (b) (6)	20 Jan 2021 16:11:27

US3672163
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 09:21:33
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:52:33
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:06:07
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 13:35:10
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 05:36:16

US3672163
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 09:21:33
Was the participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:22:42
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Jan 2021 16:11:27

US3672163
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 09:21:33
Under what version of the Protocol was the Participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:52:33
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	16 Apr 2021 15:06:07
User closed query 'Per CDM, per sponsor review: Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 13:17:33
Query 'Per CDM, per sponsor review: Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 13:35:13
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4), (b) (6)	09 Apr 2021 13:35:10
User opened query 'Per CDM, per sponsor review: Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 08:11:31
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 05:36:16

US3672163
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 09:21:33
Date of unblinding *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:22:42
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:57:43
User entered '19 Jan 2021'	(b) (4), (b) (6)	20 Jan 2021 16:11:27

US3672163
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 09:21:33
Participant randomization assignment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:22:42
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:57:43
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	20 Jan 2021 16:11:27

US3672163
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 09:21:33
Actual Dose 1

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:22:42
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:57:43
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	20 Jan 2021 16:11:27

US3672163
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 09:21:33
Actual Dose 2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:22:42
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
User entered 'Not Administered (NA)'	(b) (4), (b) (6)	20 Jan 2021 16:11:27

US3672163
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 09:21:33
Will participant receive mRNA-1273?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:22:42
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:57:43
User entered 'No (N)'	(b) (4), (b) (6)	20 Jan 2021 16:11:27

US3672163
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 09:21:33
Placebo Only Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User entered empty.	System	20 Jan 2021 16:11:27

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US3672163
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 09:21:33
Continuing with mRNA-1273

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User entered empty.	System	20 Jan 2021 16:11:27

FDA-CBER-2022-1614-2937465

US3672163
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:21:33
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:22:54
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:57:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Jan 2021 16:12:21

FDA-CBER-2022-1614-2937466

US3672163
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:21:33
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User closed query 'The Collection Date is greater than the Date of study discontinuation/completion. Please review and reconcile.' (Site from System).	System	08 Apr 2021 17:53:29
User opened query 'The Collection Date is greater than the Date of study discontinuation/completion. Please review and reconcile.' (Site from System).	System	01 Apr 2021 14:30:26
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:22:54
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:57:43
User entered '19 Jan 2021'	(b) (4), (b) (6) (b) (4)	20 Jan 2021 16:12:21

US3672163
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:21:33
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:22:54
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:57:43
User entered '16:47'	(b) (4), (b) (6)	20 Jan 2021 16:12:21

US3672163
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:21:33
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User entered '19 Jan 2021 16:47'	System	20 Jan 2021 16:12:21

FDA-CBER-2022-1614-2937469

US3672163
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 10 Jun 2021 09:21:33
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:23:17
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Jan 2021 16:11:47

US3672163
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 10 Jun 2021 09:21:33
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User closed query 'Collection Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	08 Apr 2021 17:53:29
User opened query 'Collection Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	01 Apr 2021 14:30:26
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:23:17
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:57:43
User entered '19 Jan 2021'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 16:11:47

FDA-CBER-2022-1614-2937471

US3672163
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 10 Jun 2021 09:21:33
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:23:17
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
User entered '16:28' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Jan 2021 16:12:07
User entered '16:47'	(b) (4), (b) (6)	20 Jan 2021 16:11:47

US3672163
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 10 Jun 2021 09:21:33
Collection Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User entered '19 Jan 2021 16:28'	System	20 Jan 2021 16:12:07
User entered '19 Jan 2021 16:47'	System	20 Jan 2021 16:11:47

US3672163
Folder: Unscheduled 27 Aug 2020
Form: Unscheduled Visit Assessment
Generated On: 10 Jun 2021 09:21:33
Visit Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:02:22
User entered '27 Aug 2020'	(b) (4), (b) (6)	28 Aug 2020 21:00:16

FDA-CBER-2022-1614-2937474

US3672163
Folder: Unscheduled 27 Aug 2020
Form: Unscheduled Visit Assessment
Generated On: 10 Jun 2021 09:21:33
Physical Exam

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:02:22
User entered '1'	(b) (4), (b) (6)	28 Aug 2020 21:00:16

FDA-CBER-2022-1614-2937475

US3672163
Folder: Unscheduled 27 Aug 2020
Form: Unscheduled Visit Assessment
Generated On: 10 Jun 2021 09:21:33
Vital Signs

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:02:22
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 21:00:16

FDA-CBER-2022-1614-2937476

US3672163
Folder: Unscheduled 27 Aug 2020
Form: Unscheduled Visit Assessment
Generated On: 10 Jun 2021 09:21:33
Immunogenicity Assessment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:02:22
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 21:00:16

FDA-CBER-2022-1614-2937477

US3672163
Folder: Unscheduled 27 Aug 2020
Form: Unscheduled Visit Assessment
Generated On: 10 Jun 2021 09:21:33
Pregnancy Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:02:22
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 21:00:16

US3672163
Folder: Unscheduled 27 Aug 2020
Form: Physical Examination
Generated On: 10 Jun 2021 09:21:33
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:02:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Aug 2020 20:11:48

FDA-CBER-2022-1614-2937479

US3672163
Folder: Unscheduled 27 Aug 2020
Form: Physical Examination
Generated On: 10 Jun 2021 09:21:33
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:02:42
User entered '27 Aug 2020'	(b) (4), (b) (6)	31 Aug 2020 20:11:48

FDA-CBER-2022-1614-2937480

US3672163
Folder: Adverse Events
Form: Adverse Events Summary
Generated On: 10 Jun 2021 09:21:33
Did the participant experience any adverse events?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:02:48
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Aug 2020 20:06:49
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Aug 2020 21:02:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 21:00:45

US3672163
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:21:33
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27

FDA-CBER-2022-1614-2937482

US3672163
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:21:33
Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 18:22:01
User closed query 'Per DM CLR - RQ: Site's response noted. However, please review and reflect the specific Type (e.g., Macular, Papular, etc) of ERYTHEMA. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 18:28:47
Query 'Per DM CLR - RQ: Site's response noted. However, please review and reflect the specific Type (e.g., Macular, Papular, etc) of ERYTHEMA. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' answered with 'unknown' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 20:16:42
User opened query 'Per DM CLR - RQ: Site's response noted. However, please review and reflect the specific Type (e.g., Macular, Papular, etc) of ERYTHEMA. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 00:02:21
User closed query 'Per DM CLR: Please review and reflect the specific type (e.g., Macular, Papular, etc) of ERYTHEMA and if it is Urticarial or Non-Urticarial. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 07:58:59
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Angioedema and urticaria, HLT: Urticarias, PT: Urticaria, LLT: Erythema urticarial - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Oct 2020 22:27:36
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Oct 2020 22:27:36

US3672163
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:21:33
Adverse event

Audit	User	Time (GMT)
Query 'Per DM CLR: Please review and reflect the specific type (e.g., Macular, Papular, etc) of ERYTHEMA and if it is Urticarial or Non-Urticarial. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 13:25:00
Data point term sent to Coder	System	23 Oct 2020 13:23:39
DataPoint Un-verified.	(b) (4), (b) (6)	23 Oct 2020 13:23:25
Coding entries removed.	(b) (4), (b) (6)	23 Oct 2020 13:23:25
User entered 'RIGHT ARM ERYTHEMA (Urticarial)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Oct 2020 13:23:25
User opened query 'Per DM CLR: Please review and reflect the specific type (e.g., Macular, Papular, etc) of ERYTHEMA and if it is Urticarial or Non-Urticarial. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 09:51:58
Query 'Per DM CLR: Please review and reflect the ERYTHEMA is Urticarial or Non-Urticarial. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' canceled (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 09:51:53
User opened query 'Per DM CLR: Please review and reflect the ERYTHEMA is Urticarial or Non-Urticarial. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 11:32:32
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:03:47
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Erythemas, PT: Erythema, LLT: Erythema - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 02:58:35
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 02:58:35
Data point term sent to Coder	System	31 Aug 2020 20:10:15

US3672163
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:21:33
Adverse event

Audit	User	Time (GMT)
User entered 'Right Arm Erythema'	(b) (4), (b) (6)	31 Aug 2020 20:09:18

US3672163
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:21:33
Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:03:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Aug 2020 20:09:18

US3672163
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:21:33
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 18:22:09
User closed query 'Per DM CLR: Note, solicited reactions are only reported as AE if it meets AE reporting criteria. This AE started at after Day 7 (onwards), review if this is considered as unsolicited event per protocol. If yes, update this field to No. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 08:21:25
Query 'Per DM CLR: Note, solicited reactions are only reported as AE if it meets AE reporting criteria. This AE started at after Day 7 (onwards), review if this is considered as unsolicited event per protocol. If yes, update this field to No. Else, provide clarification.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 17:47:16
DataPoint Un-verified.	(b) (4), (b) (6)	23 Sep 2020 17:46:15
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Sep 2020 17:46:15
User opened query 'Per DM CLR: Note, solicited reactions are only reported as AE if it meets AE reporting criteria. This AE started at after Day 7 (onwards), review if this is considered as unsolicited event per protocol. If yes, update this field to No. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 11:32:40
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:03:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Aug 2020 20:09:18

US3672163
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:21:33
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:03:47
User entered 'No (N)'	(b) (4), (b) (6)	31 Aug 2020 20:09:18

US3672163
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:21:33
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:03:47
User entered '26 Aug 2020'	(b) (4), (b) (6)	31 Aug 2020 20:09:18

US3672163
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:21:33
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:03:47
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 20:09:18

US3672163
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:21:33
AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User entered empty.	System	31 Aug 2020 20:09:18

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US3672163
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:21:33
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 18:22:13
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 06:42:58
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 12:45:13
DataPoint Un-verified.	(b) (4), (b) (6)	18 Dec 2020 12:45:07
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Dec 2020 12:45:07
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 01:09:10
User closed query 'Per source, AE resolved on 02Sep2020. Please verify and update accordingly. Thanks!' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 15:34:29
Query 'Per source, AE resolved on 02Sep2020. Please verify and update accordingly. Thanks!' answered with 'confirm ongoing' (Site from CRA).	(b) (4), (b) (6)	23 Sep 2020 17:47:23
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 14:41:21
User opened query 'Per source, AE resolved on 02Sep2020. Please verify and update accordingly. Thanks!' (Site from CRA).	(b) (4), (b) (6)	23 Sep 2020 14:41:07
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 20:04:37
DataPoint Un-verified.	(b) (4), (b) (6)	14 Sep 2020 18:56:12

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US3672163
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:21:33
Ongoing?

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 18:56:12
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:03:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Aug 2020 20:09:18

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US3672163
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:21:33
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 18:22:15
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Dec 2020 21:16:54
User entered '1 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Dec 2020 21:16:54
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Dec 2020 21:16:34
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Dec 2020 21:16:34
User entered ' Oct 2020' (non-conformant).	(b) (4), (b) (6)	21 Dec 2020 21:16:34
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	18 Dec 2020 20:38:39
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	18 Dec 2020 20:38:39
User entered 'UN Oct 2020' (non-conformant).	(b) (4), (b) (6)	18 Dec 2020 20:38:39
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	18 Dec 2020 20:37:24
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	18 Dec 2020 20:37:24
User entered '00 Oct 2020' (non-conformant).	(b) (4), (b) (6)	18 Dec 2020 20:37:24
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	18 Dec 2020 20:37:13
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	18 Dec 2020 20:37:13
User entered 'UN Oct 2020' (non-conformant).	(b) (4), (b) (6)	18 Dec 2020 20:37:13
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	18 Dec 2020 20:37:01
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	18 Dec 2020 20:37:01
User entered 'UK Oct 2020' (non-conformant).	(b) (4), (b) (6)	18 Dec 2020 20:37:01
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	18 Dec 2020 12:45:07

US3672163
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:21:33
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	18 Dec 2020 12:45:07
User entered 'un Oct 2020' (non-conformant).	(b) (4), (b) (6)	18 Dec 2020 12:45:07
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 14:41:21
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	14 Sep 2020 20:04:49
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	14 Sep 2020 20:04:49
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	14 Sep 2020 20:04:37
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 20:04:37
DataPoint Un-verified.	(b) (4), (b) (6)	14 Sep 2020 18:56:12
User entered '2 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 18:56:12
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:03:47
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 20:09:18

US3672163
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:21:33
End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:03:47
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 20:09:18

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US3672163
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:21:33
AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User entered empty.	System	31 Aug 2020 20:09:18

US3672163
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:21:33
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:03:47
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	31 Aug 2020 20:09:18

US3672163
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:21:33
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:03:47
User entered 'No (N)'	(b) (4), (b) (6)	31 Aug 2020 20:09:18

US3672163
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:21:33
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:03:47
User entered '0'	(b) (4), (b) (6)	31 Aug 2020 20:09:18

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US3672163
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:21:33
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:03:47
User entered '0'	(b) (4), (b) (6)	31 Aug 2020 20:09:18

US3672163
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:21:33
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:03:47
User entered '0'	(b) (4), (b) (6)	31 Aug 2020 20:09:18

US3672163
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:21:33
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:03:47
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 20:09:18

US3672163
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:21:33
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:03:47
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 20:09:18

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US3672163
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:21:33
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:03:47
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 20:09:18

US3672163
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:21:33
Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:03:47
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 20:09:18

US3672163
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:21:33
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:03:47
User entered '0'	(b) (4), (b) (6)	31 Aug 2020 20:09:18

US3672163
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:21:33
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:03:47
User entered '0'	(b) (4), (b) (6)	31 Aug 2020 20:09:18

US3672163
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:21:33
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:03:47
User entered '0'	(b) (4), (b) (6)	31 Aug 2020 20:09:18

US3672163
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:21:33
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:03:47
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 20:09:44
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Aug 2020 20:09:44
User entered 'Related (RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Aug 2020 20:09:44
User opened query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 20:09:18
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 20:09:18

US3672163
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:21:33
Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:03:47
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 20:09:44
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Aug 2020 20:09:44
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Aug 2020 20:09:44
User opened query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 20:09:18
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 20:09:18

US3672163
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:21:33
Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
User closed query 'Per DM CLR - RQ: Site's response noted. However, please verify what has been "confirm" as the Dosing discontinuation page is still blank. Review and update applicable eCRF as appropriate. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 03:37:27
Query 'Per DM CLR - RQ: Site's response noted. However, please verify what has been "confirm" as the Dosing discontinuation page is still blank. Review and update applicable eCRF as appropriate. Else, clarify.' answered with 'dosing discontinuation completed' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 13:23:49
User opened query 'Per DM CLR - RQ: Site's response noted. However, please verify what has been "confirm" as the Dosing discontinuation page is still blank. Review and update applicable eCRF as appropriate. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 11:56:49
User closed query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. Ensure this is reflected in treatment discontinuation if applicable. Review and update. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 13:32:23
Query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. Ensure this is reflected in treatment discontinuation if applicable. Review and update. Else, clarify.' answered with 'confirm' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 17:47:34
User opened query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. Ensure this is reflected in treatment discontinuation if applicable. Review and update. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 11:32:24
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:03:47
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 20:09:44
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Aug 2020 20:09:44

US3672163
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:21:33
Action taken with investigational product

Audit	User	Time (GMT)
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Aug 2020 20:09:44
User opened query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 20:09:18
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 20:09:18

US3672163
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:21:33
None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:03:47
User entered '1'	(b) (4), (b) (6)	31 Aug 2020 20:09:18

FDA-CBER-2022-1614-2937514

US3672163
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:21:33
Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:03:47
User entered '0'	(b) (4), (b) (6)	31 Aug 2020 20:09:18

US3672163
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:21:33
Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:03:47
User entered '0'	(b) (4), (b) (6)	31 Aug 2020 20:09:18

US3672163
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:21:33
Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 18:22:22
DataPoint Un-verified.	(b) (4), (b) (6)	18 Dec 2020 12:45:07
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Dec 2020 12:45:07
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 14:41:21
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 20:04:49
DataPoint Un-verified.	(b) (4), (b) (6)	14 Sep 2020 18:56:12
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 18:56:12
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:03:47
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	31 Aug 2020 20:09:18

US3672163
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:21:33
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:03:47
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 20:09:18

US3672163
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:21:33
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:03:47
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 20:09:18

FDA-CBER-2022-1614-2937519

US3672163
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:21:33
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User entered '0'	System	31 Aug 2020 20:09:18

US3672163
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:21:33
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User entered '1'	System	31 Aug 2020 20:09:18

US3672163
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:21:33
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27

US3672163
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:21:33
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27

FDA-CBER-2022-1614-2937523

US3672163
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:21:33
Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:03:47
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: General signs and symptoms NEC, PT: Induration, LLT: Induration - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 11:11:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 11:11:45
Data point term sent to Coder	System	31 Aug 2020 20:11:20
User entered 'Right Arm Induration'	(b) (4), (b) (6)	31 Aug 2020 20:10:57

US3672163
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:21:33
Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:03:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Aug 2020 20:10:57

US3672163
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:21:33
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 18:22:30
User closed query 'Per DM CLR: Note, solicited reactions are only reported as AE if it meets AE reporting criteria. This AE started at after Day 7 (onwards), review if this is considered as unsolicited event per protocol. If yes, update this field to No. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 08:24:56
Query 'Per DM CLR: Note, solicited reactions are only reported as AE if it meets AE reporting criteria. This AE started at after Day 7 (onwards), review if this is considered as unsolicited event per protocol. If yes, update this field to No. Else, provide clarification.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 17:51:10
DataPoint Un-verified.	(b) (4), (b) (6)	23 Sep 2020 17:51:03
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Sep 2020 17:51:03
User opened query 'Per DM CLR: Note, solicited reactions are only reported as AE if it meets AE reporting criteria. This AE started at after Day 7 (onwards), review if this is considered as unsolicited event per protocol. If yes, update this field to No. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 11:33:11
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:03:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Aug 2020 20:10:57

US3672163
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:21:33
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:03:47
User entered 'No (N)'	(b) (4), (b) (6)	31 Aug 2020 20:10:57

FDA-CBER-2022-1614-2937527

US3672163
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:21:33
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:03:47
User entered '26 Aug 2020'	(b) (4), (b) (6)	31 Aug 2020 20:10:57

FDA-CBER-2022-1614-2937528

US3672163
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:21:33
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:03:47
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 20:10:57

US3672163
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:21:33
AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User entered empty.	System	31 Aug 2020 20:10:57

US3672163
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:21:33
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 14:41:21
DataPoint Un-verified.	(b) (4), (b) (6)	14 Sep 2020 18:56:39
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 18:56:39
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:03:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Aug 2020 20:10:57

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US3672163
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:21:33
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 14:41:21
DataPoint Un-verified.	(b) (4), (b) (6)	14 Sep 2020 18:56:39
User entered '2 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 18:56:39
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:03:47
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 20:10:57

US3672163
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:21:33
End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:03:47
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 20:10:57

US3672163
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:21:33
AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User entered empty.	System	31 Aug 2020 20:10:57

US3672163
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:21:33
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:03:47
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	31 Aug 2020 20:10:57

US3672163
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:21:33
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:03:47
User entered 'No (N)'	(b) (4), (b) (6)	31 Aug 2020 20:10:57

US3672163
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:21:33
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:03:47
User entered '0'	(b) (4), (b) (6)	31 Aug 2020 20:10:57

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US3672163
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:21:33
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:03:47
User entered '0'	(b) (4), (b) (6)	31 Aug 2020 20:10:57

US3672163
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:21:33
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:03:47
User entered '0'	(b) (4), (b) (6)	31 Aug 2020 20:10:57

FDA-CBER-2022-1614-2937539

US3672163
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:21:33
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:03:47
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 20:10:57

FDA-CBER-2022-1614-2937540

US3672163
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:21:33
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:03:47
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 20:10:57

FDA-CBER-2022-1614-2937541

US3672163
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:21:33
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:03:47
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 20:10:57

US3672163
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:21:33
Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:03:47
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 20:10:57

FDA-CBER-2022-1614-2937543

US3672163
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:21:33
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:03:47
User entered '0'	(b) (4), (b) (6)	31 Aug 2020 20:10:57

US3672163
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:21:33
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:03:47
User entered '0'	(b) (4), (b) (6)	31 Aug 2020 20:10:57

US3672163
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:21:33
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:03:47
User entered '0'	(b) (4), (b) (6)	31 Aug 2020 20:10:57

FDA-CBER-2022-1614-2937546

US3672163
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:21:33
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:03:47
User entered 'Related (RELATED)'	(b) (4), (b) (6)	31 Aug 2020 20:10:57

FDA-CBER-2022-1614-2937547

US3672163
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:21:33
Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:03:47
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	31 Aug 2020 20:10:57

FDA-CBER-2022-1614-2937548

US3672163
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:21:33
Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
User closed query 'Per DM CLR - RQ: Site's response noted. However, please verify what has been "confirm" as the Dosing discontinuation page is still blank. Review and update applicable eCRF as appropriate. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 03:37:49
Query 'Per DM CLR - RQ: Site's response noted. However, please verify what has been "confirm" as the Dosing discontinuation page is still blank. Review and update applicable eCRF as appropriate. Else, clarify. ' answered with 'dosing discontinuation upated' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 13:25:14
User opened query 'Per DM CLR - RQ: Site's response noted. However, please verify what has been "confirm" as the Dosing discontinuation page is still blank. Review and update applicable eCRF as appropriate. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 11:57:19
User closed query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. Ensure this is reflected in treatment discontinuation if applicable. Review and update. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 12:12:25
Query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. Ensure this is reflected in treatment discontinuation if applicable. Review and update. Else, clarify.' answered with 'confirm' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 17:50:36
User opened query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. Ensure this is reflected in treatment discontinuation if applicable. Review and update. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 11:33:02
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:03:47

US3672163
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:21:33
Action taken with investigational product

Audit	User	Time (GMT)
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	(b) (4), (b) (6)	31 Aug 2020 20:10:57

US3672163
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:21:33
None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:03:47
User entered '1'	(b) (4), (b) (6)	31 Aug 2020 20:10:57

US3672163
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:21:33
Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:03:47
User entered '0'	(b) (4), (b) (6)	31 Aug 2020 20:10:57

US3672163
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:21:33
Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:03:47
User entered '0'	(b) (4), (b) (6)	31 Aug 2020 20:10:57

US3672163
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:21:33
Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 14:41:21
DataPoint Un-verified.	(b) (4), (b) (6)	14 Sep 2020 18:56:39
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 18:56:39
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:03:47
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	31 Aug 2020 20:10:57

US3672163
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:21:33
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:03:47
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 20:10:57

US3672163
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:21:33
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:03:47
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 20:10:57

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US3672163
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:21:33
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User entered '0'	System	31 Aug 2020 20:10:57

US3672163
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:21:33
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User entered '1'	System	31 Aug 2020 20:10:57

US3672163
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:21:33
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27

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US3672163
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination Summary
Generated On: 10 Jun 2021 09:21:33
Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:03:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 15:34:21

US3672163
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:21:33
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:36:51
User closed query 'Please revise spelling of medication to CHOLESTRYAMINE as a 0 is currently entered instead of the expected O. ' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 15:36:41
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS, ATC: OTHER ANTIDIARRHEALS, ATC: OTHER ANTIDIARRHEALS, PRODUCT: COLESTYRAMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Oct 2020 11:58:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Oct 2020 11:58:36
Query 'Please revise spelling of medication to CHOLESTRYAMINE as a 0 is currently entered instead of the expected O. ' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	20 Oct 2020 14:42:53
Data point term sent to Coder	System	20 Oct 2020 14:42:39
DataPoint Un-verified.	(b) (4), (b) (6)	20 Oct 2020 14:42:34
Coding entries removed.	(b) (4), (b) (6)	20 Oct 2020 14:42:34
User entered 'CHOLESTRYRAMINE' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Oct 2020 14:42:34
User opened query 'Please revise spelling of medication to CHOLESTRYAMINE as a 0 is currently entered instead of the expected O. ' (Site from CRA).	(b) (4), (b) (6)	19 Oct 2020 16:05:15
Query 'Please revise spelling of medication to CHOLESTRYAMINE as a 0 is currently entered instead of the expected O.' canceled (Site from CRA).	(b) (4), (b) (6)	19 Oct 2020 16:04:16

US3672163
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:21:33
Name of Medication

Audit	User	Time (GMT)
User opened query 'Please revise spelling of medication to CHOLESTRYAMINE as a 0 is currently entered instead of the expected O.' (Site from CRA).	(b) (4), (b) (6)	19 Oct 2020 16:04:01
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:04:08
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS, ATC: OTHER ANTIDIARRHEALS, ATC: OTHER ANTIDIARRHEALS, PRODUCT: COLESTYRAMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 12:21:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 12:21:16
Data point term sent to Coder	System	20 Aug 2020 15:36:24
User entered 'CH0LESTRYRAMINE'	(b) (4), (b) (6)	20 Aug 2020 15:36:05

US3672163
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:21:33
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:04:08
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 15:36:05

US3672163
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:21:33
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:04:08
User entered 'INTERRMITTENT POST - CHOLECYSTERECTOMY DIARRHEA'	(b) (4), (b) (6)	20 Aug 2020 15:36:05

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US3672163
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:21:33
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:57:43
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of number of dose/s as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Oct 2020 17:45:23
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:36:49
Query 'Per DM CLR: Please provide the actual dose for this medication instead of number of dose/s as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 14:42:57
DataPoint Un-verified.	(b) (4), (b) (6)	20 Oct 2020 14:42:34
User entered '4' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Oct 2020 14:42:34
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of number of dose/s as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Oct 2020 10:16:50
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:04:08
User entered '1'	(b) (4), (b) (6)	20 Aug 2020 15:36:05

US3672163
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:21:33
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:36:45
User closed query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	20 Oct 2020 14:43:03
User opened query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	20 Oct 2020 14:42:34
DataPoint Un-verified.	(b) (4), (b) (6)	20 Oct 2020 14:42:34
User entered 'g (g)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Oct 2020 14:42:34
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:04:08
User entered 'Other (OTHER)'	(b) (4), (b) (6)	20 Aug 2020 15:36:05

US3672163
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:21:33
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:36:43
DataPoint Un-verified.	(b) (4), (b) (6)	20 Oct 2020 14:43:03
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Oct 2020 14:43:03
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:04:08
User entered 'DOSE'	(b) (4), (b) (6)	20 Aug 2020 15:36:05

US3672163
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:21:33
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:04:08
User entered 'as needed (PRN)'	(b) (4), (b) (6)	20 Aug 2020 15:36:05

US3672163
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:21:33
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:04:08
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 15:36:05

US3672163
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:21:33
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:04:08
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	20 Aug 2020 15:36:05

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US3672163
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:21:33
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:04:08
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 15:36:05

US3672163
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:21:33
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:04:08
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:20:22
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'PATIENT IS STILL TAKING CON MED.' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 15:36:49
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 15:36:05
User entered 'UN UNK 2018'	(b) (4), (b) (6)	20 Aug 2020 15:36:05

US3672163
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:21:33
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:04:08
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 15:36:05

US3672163
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:21:33
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:04:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 15:36:05

US3672163
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:21:33
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:04:08
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 15:36:05

US3672163
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:21:33
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:04:08
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Aug 2020 15:36:25
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Aug 2020 15:36:25
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Aug 2020 15:36:25
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Aug 2020 15:36:05
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 15:36:05

US3672163
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:21:33
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User entered empty.	System	20 Aug 2020 15:36:05

US3672163
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:21:33
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User entered empty.	System	20 Aug 2020 15:36:05

US3672163
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:21:33
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User entered empty.	System	20 Aug 2020 15:36:05

US3672163
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:21:33
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: OTHER GYNECOLOGICALS, ATC: OTHER GYNECOLOGICALS, ATC: OTHER GYNECOLOGICALS, PRODUCT: PAROXETINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 14:44:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 14:44:43
Data point term sent to Coder	System	20 Oct 2020 14:43:42
Coding entries removed.	(b) (4), (b) (6)	20 Oct 2020 14:43:20
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:04:08
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: OTHER GYNECOLOGICALS, ATC: OTHER GYNECOLOGICALS, ATC: OTHER GYNECOLOGICALS, PRODUCT: PAROXETINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 05:45:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 05:45:44
Data point term sent to Coder	System	20 Aug 2020 15:38:35
User entered 'PAROXETINE'	(b) (4), (b) (6)	20 Aug 2020 15:37:45

US3672163
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:21:33
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:04:08
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 15:37:45

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US3672163
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:21:33
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 18:23:36
User closed query 'Please consider if the indication for this concomitant medication would be more properly captured as VASOMOTOR SYMPTOMS.' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 15:34:51
Query 'Please consider if the indication for this concomitant medication would be more properly captured as VASOMOTOR SYMPTOMS.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	20 Oct 2020 14:43:30
DataPoint Un-verified.	(b) (4), (b) (6)	20 Oct 2020 14:43:20
User entered 'VASOMOTOR SYMPTOMS' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Oct 2020 14:43:20
User opened query 'Please consider if the indication for this concomitant medication would be more properly captured as VASOMOTOR SYMPTOMS.' (Site from CRA).	(b) (4), (b) (6)	19 Oct 2020 16:07:18
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:04:08
User entered 'VASCOMOTOR SYMPTOMS'	(b) (4), (b) (6)	20 Aug 2020 15:37:45

US3672163
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:21:33
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:04:08
User entered '10'	(b) (4), (b) (6)	20 Aug 2020 15:37:45

US3672163
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:21:33
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:04:08
User entered 'mg (mg)'	(b) (4), (b) (6)	20 Aug 2020 15:37:45

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US3672163
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:21:33
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:04:08
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 15:37:45

US3672163
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:21:33
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:04:08
User entered 'once daily (QD)'	(b) (4), (b) (6)	20 Aug 2020 15:37:45

US3672163
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:21:33
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:04:08
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 15:37:45

FDA-CBER-2022-1614-2937587

US3672163
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:21:33
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:04:08
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	20 Aug 2020 15:37:45

FDA-CBER-2022-1614-2937588

US3672163
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:21:33
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:04:08
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 15:37:45

US3672163
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:21:33
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:04:08
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:20:22
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'PATIENT IS STILL TAKING CON MED.' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 15:38:33
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 15:37:45
User entered 'UN UNK 2017'	(b) (4), (b) (6)	20 Aug 2020 15:37:45

US3672163
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:21:33
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:04:08
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 15:37:45

US3672163
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:21:33
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:04:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 15:37:45

FDA-CBER-2022-1614-2937592

US3672163
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:21:33
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:04:08
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 15:37:45

US3672163
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:21:33
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:04:08
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 15:37:45

US3672163
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:21:33
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User entered '1'	System	20 Aug 2020 15:37:45

US3672163
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:21:33
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User entered '1'	System	20 Aug 2020 15:37:45

FDA-CBER-2022-1614-2937596

US3672163
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:21:33
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User entered '804 (804)'	System	20 Aug 2020 15:37:45

FDA-CBER-2022-1614-2937597

US3672163
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:21:33
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:04:08
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: AMINOALKYL ETHERS, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE, PRODUCTSYNONYM: BENADRYL [DIPHENHYDRAMINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 15:41:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 15:41:23
Data point term sent to Coder	System	20 Aug 2020 15:40:40
User entered 'BENADRYL'	(b) (4), (b) (6)	20 Aug 2020 15:39:48

US3672163
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:21:33
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:04:08
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 15:39:48

FDA-CBER-2022-1614-2937599

US3672163
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:21:33
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:04:08
User entered 'SEASONAL ALLERGIES'	(b) (4), (b) (6)	20 Aug 2020 15:39:48

US3672163
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:21:33
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 18:23:44
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 17:45:41
Query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 14:44:16
DataPoint Un-verified.	(b) (4), (b) (6)	20 Oct 2020 14:44:12
User entered '25' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Oct 2020 14:44:12
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Oct 2020 10:17:00
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:04:08
User entered '1'	(b) (4), (b) (6)	20 Aug 2020 15:39:48

US3672163
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:21:33
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 18:23:46
DataPoint Un-verified.	(b) (4), (b) (6)	20 Oct 2020 14:44:12
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Oct 2020 14:44:12
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:04:08
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	20 Aug 2020 15:39:48

US3672163
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:21:33
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:04:08
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 15:39:48

US3672163
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:21:33
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 18:23:50
DataPoint Un-verified.	(b) (4), (b) (6)	20 Oct 2020 14:44:12
User entered 'as needed (PRN)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Oct 2020 14:44:12
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:04:08
User entered 'once daily (QD)'	(b) (4), (b) (6)	20 Aug 2020 15:39:48

US3672163
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:21:33
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:04:08
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 15:39:48

US3672163
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:21:33
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:04:08
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	20 Aug 2020 15:39:48

FDA-CBER-2022-1614-2937606

US3672163
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:21:33
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:04:08
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 15:39:48

US3672163
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:21:33
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:04:08
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:20:22
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'PATIENT IS STILL TAKING CON MED. ' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 15:40:05
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 15:39:48
User entered 'UN UNK 2016'	(b) (4), (b) (6)	20 Aug 2020 15:39:48

US3672163
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:21:33
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:04:08
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 15:39:48

US3672163
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:21:33
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:04:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 15:39:48

US3672163
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:21:33
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:04:08
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 15:39:48

US3672163
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:21:33
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 16:04:08
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 15:39:48

US3672163
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:21:33
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User entered empty.	System	20 Oct 2020 14:44:12
User entered '1'	System	20 Aug 2020 15:39:48

US3672163
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:21:33
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User entered empty.	System	20 Oct 2020 14:44:12
User entered '1'	System	20 Aug 2020 15:39:48

US3672163
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:21:33
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User entered empty.	System	20 Oct 2020 14:44:12
User entered '804 (804)'	System	20 Aug 2020 15:39:48

US3672163
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:21:33
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 18:37:43
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Jan 2021 16:16:05
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Jan 2021 16:16:05
Data point term sent to Coder	System	20 Jan 2021 16:15:00
User entered 'influenza vaccine'	(b) (4), (b) (6)	20 Jan 2021 16:14:13

US3672163
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:21:33
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 18:37:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Jan 2021 16:14:13

US3672163
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:21:33
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 18:37:43
User entered 'influenza prophylaxis'	(b) (4), (b) (6)	20 Jan 2021 16:14:13

US3672163
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:21:33
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 18:37:43
User entered '1'	(b) (4), (b) (6)	20 Jan 2021 16:14:13

US3672163
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:21:33
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 18:37:43
User entered 'Other (OTHER)'	(b) (4), (b) (6)	20 Jan 2021 16:14:13

US3672163
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:21:33
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 18:37:43
User entered 'injection'	(b) (4), (b) (6)	20 Jan 2021 16:14:13

US3672163
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:21:33
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 18:37:43
User entered 'once (ONCE)'	(b) (4), (b) (6)	20 Jan 2021 16:14:13

US3672163
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:21:33
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 18:37:43
User entered empty.	(b) (4), (b) (6)	20 Jan 2021 16:14:13

US3672163
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:21:33
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 18:37:43
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4), (b) (6)	20 Jan 2021 16:14:13

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US3672163
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:21:33
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 18:37:43
User entered empty.	(b) (4), (b) (6)	20 Jan 2021 16:14:13

US3672163
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:21:33
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User closed query 'Start Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	08 Apr 2021 17:53:29
User opened query 'Start Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	01 Apr 2021 14:30:26
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 18:37:43
User entered '15 Dec 2020'	(b) (4), (b) (6)	20 Jan 2021 16:14:13

US3672163
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:21:33
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 18:37:43
User entered '0'	(b) (4), (b) (6)	20 Jan 2021 16:14:13

US3672163
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:21:33
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 18:37:43
User entered 'No (N)'	(b) (4), (b) (6)	20 Jan 2021 16:14:13

US3672163
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:21:33
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User closed query 'End Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	08 Apr 2021 17:53:29
User opened query 'End Date is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	01 Apr 2021 14:30:26
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 18:37:43
User entered '15 Dec 2020'	(b) (4), (b) (6)	20 Jan 2021 16:14:13

US3672163
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:21:33
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 18:37:43
User entered 'No (N)'	(b) (4), (b) (6)	20 Jan 2021 16:14:13

US3672163
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:21:33
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User entered empty.	System	20 Jan 2021 16:14:13

US3672163
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:21:33
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User entered empty.	System	20 Jan 2021 16:14:13

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US3672163
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:21:33
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User entered empty.	System	20 Jan 2021 16:14:13

US3672163
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures Summary
Generated On: 10 Jun 2021 09:21:33
Were any concomitant procedures performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	16 Apr 2021 15:06:07
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:19:21
User entered 'No (N)'	(b) (4), (b) (6)	08 Mar 2021 21:32:31

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US3672163
Folder: End of Study (1)
Form: Dosing Discontinuation
Generated On: 10 Jun 2021 09:21:33
Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:19:48
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:57:43
User entered '28 Aug 2020'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 13:24:48

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US3672163
Folder: End of Study (1)
Form: Dosing Discontinuation
Generated On: 10 Jun 2021 09:21:33
Primary reason for dosing discontinuation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:19:48
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:57:43
User entered 'AE (specify) (ADVERSE EVENT)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 13:24:48

US3672163
Folder: End of Study (1)
Form: Dosing Discontinuation
Generated On: 10 Jun 2021 09:21:33
If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 18:19:48
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:57:43
User closed query 'Per CDM: Per sponsor review, please consider updating specify field to include only AE, number sign, and number. (i.e. AE #2). Thank you. ' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 10:46:24
Query 'Per CDM: Per sponsor review, please consider updating specify field to include only AE, number sign, and number. (i.e. AE #2). Thank you. ' answered with 'OK' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 14:22:23
User entered 'AE#2, AE# 3' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 14:22:16
User opened query 'Per CDM: Per sponsor review, please consider updating specify field to include only AE, number sign, and number. (i.e. AE #2). Thank you. ' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 14:13:31
User closed query 'Per CDM: Please record AE record number instead of details ' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 02:21:00
Query 'Per CDM: Please record AE record number instead of details ' answered with 'done' (Site from DM).	Patty Howenstine (b) (4) (b) (4)	24 Feb 2021 17:30:02
User entered 'AE 2 and 3' reason for change: Data Entry Error	Patty Howenstine (b) (4) (b) (4)	24 Feb 2021 17:29:57
User opened query 'Per CDM: Please record AE record number instead of details ' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 14:27:49
User entered 'right arm erythema, right arm induration'	(b) (4), (b) (6)	23 Oct 2020 13:24:48

US3672163
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 10 Jun 2021 09:21:33
Date of study discontinuation/completion *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:53:01
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	16 Apr 2021 15:06:07
User closed query 'Subject was discontinued from dosing, however, they are still receiving calls and coming in for visits. Please consider revising this CRF as the subject is still in the study.' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 14:57:03
Query 'Subject was discontinued from dosing, however, they are still receiving calls and coming in for visits. Please consider revising this CRF as the subject is still in the study.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 17:53:36
User entered '01 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 17:53:29
User opened query 'Subject was discontinued from dosing, however, they are still receiving calls and coming in for visits. Please consider revising this CRF as the subject is still in the study.' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 17:40:36
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	01 Apr 2021 14:30:26
User entered '28 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Apr 2021 14:30:26
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	01 Apr 2021 14:30:14
User entered '28 Aug 2021'	(b) (4), (b) (6)	01 Apr 2021 14:30:14

US3672163
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 10 Jun 2021 09:21:33
Reason for discontinuation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:53:01
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:06:07
User entered 'AE (specify) (ADVERSE EVENT)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 14:30:14

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US3672163
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 10 Jun 2021 09:21:33
If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:53:01
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:06:07
User entered 'AE#2 & AE#3'	(b) (4), (b) (6)	01 Apr 2021 14:30:14

US3672163
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 10 Jun 2021 09:21:33
If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:53:01
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:06:07
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 14:30:14

US3672163
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 10 Jun 2021 09:21:33
If main cause of death is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:53:01
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:06:07
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 14:30:14

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US3672163
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 10 Jun 2021 09:21:33
Date of death *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:53:01
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:06:07
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 14:30:14

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US3672163
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 10 Jun 2021 09:21:33
Was autopsy performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:12:27
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:53:01
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:06:07
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 14:30:14

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