US3672203 (Prod: Coastal Carolina Research Center)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:23:55

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US3672203
Form: Participant Creation
Data signed: (b) (4) **05 Mar 2021 17:41:48**
Generated On: 10 Jun 2021 09:23:55

Participant ID	US3672203

mRNA-1273-P301 Completion Guidelines

FDA-CBER-2022-1614-2944278

US3672203
Folder: Screening
Form: Visit Date
Data signed: (b) (4) **15 Feb 2021 20:03:07**
Generated On: 10 Jun 2021 09:23:55

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	19 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	SCRN

FDA-CBER-2022-1614-2944279

US3672203
Folder: Screening
Form: Demographics
Data signed: (b) (4) **15 Feb 2021 20:03:07**
Generated On: 10 Jun 2021 09:23:55

Date of Birth (MMM yyyy)	(b) (6) 1995
Age	25
Age Units	YEARS
Age (Derived)	25
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

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US3672203
Folder: Screening
Form: Enrollment
Data signed: (b) (4) **15 Feb 2021 20:03:07**
Generated On: 10 Jun 2021 09:23:55

Date of Informed Consent *(dd MMM yyyy)*	19 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

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US3672203
Folder: Screening
Form: Inclusion/Exclusion Criteria Summary
Data signed: (b) (4) **15 Feb 2021 20:03:07**
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Did the participant meet all eligibility criteria?	Yes ■ No ☐

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US3672203
Folder: Screening
Form: Medical History Summary
Data signed: (b) (4) **15 Feb 2021 20:03:07**
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Were any significant conditions reported?	Yes ■ No ☐

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US3672203
Folder: Screening
Form: Medical History (1)
Data signed: (b) (4) **15 Feb 2021 20:03:07**
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Condition	ANXIETY
Start date (dd MMM yyyy)	UN JAN 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes ●
	No ○
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

US3672203
Folder: Screening
Form: Medical History (2)
Data signed: (b) (4) **15 Feb 2021 20:03:07**
Generated On: 10 Jun 2021 09:23:55

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

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US3672203
Folder: Screening
Form: Vital Signs
Data signed: (b) (4) **15 Feb 2021 20:03:07**
Generated On: 10 Jun 2021 09:23:55

Were vital signs assessed?	Yes ☑ / No ☐
Date of assessment *(dd MMM yyyy)*	19 AUG 2020
Time of assessment *(00:00-23:59)*	15:48 (24 HR)
Vital Signs Date and Time (derived)	19 AUG 2020 15:48
Height *(xxx.x)*	177.5 cm
Weight *(xxx.x)*	62.9 kg
BMI *(xxx.x)*	19.96429 kg/m^2
BMI units	KG/M2
Temperature *(xxx.x)*	ND - Not Done
Route of measurement	Oral ☐ / Axillary ☐ / Other ☐
If Other, specify	
Pulse *(xxx)*	ND - Not Done
Pulse units	BPM
Respiratory Rate *(xxx)*	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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US3672203
Folder: Screening
Form: Physical Examination
Data signed: (b) (4) **15 Feb 2021 20:03:07**
Generated On: 10 Jun 2021 09:23:55

Was the physical examination performed?	Yes ☑ No ☐
Date of examination *(dd MMM yyyy)*	19 AUG 2020

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

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US3672203
Folder: Screening
Form: Risk of Exposure
Data signed: (b) (4) **15 Feb 2021 20:03:07**
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Occupational Risk	
Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)	Yes ☐ No ■
Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)	Yes ☐ No ■
Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)	Yes ☐ No ■
Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)	Yes ☐ No ■
Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)	Yes ☐ No ■
Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)	Yes ☐ No ■
Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)	Yes ☐ No ■
Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)	Yes ☐ No ■
Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)	Yes ☐ No ■
Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)	Yes ☐ No ■
Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)	Yes ☐ No ■
Other	Yes ☐ No ■
Specify	
Location and Living Circumstances Risk (check all that apply)	
No Risk Identified	False
Resides in Nursing Home or Assisted Living Facility	False

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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

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US3672203
Folder: Visit 1 Day 1
Form: Visit Date
Data signed: (b) (4) **15 Feb 2021 20:03:11**
Generated On: 10 Jun 2021 09:23:55

Was this visit performed?	Yes ☑ No ☐
Visit date (dd MMM yyyy)	19 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ☑
Folder OID	VISIT1

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US3672203
Folder: Visit 1 Day 1
Form: Randomization
Data signed: (b) (4) **15 Feb 2021 20:03:11**
Generated On: 10 Jun 2021 09:23:55

What was the date of randomization? *(dd MMM yyyy)*	19 AUG 2020
What was the participant's randomization number?	106157
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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US3672203
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Data signed: (b) (4) **15 Feb 2021 20:03:11**
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Height	ND - Not Done
Weight	ND - Not Done

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US3672203
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Data signed: (b) (4) **15 Feb 2021 20:03:11**
Generated On: 10 Jun 2021 09:23:55

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)*	19 AUG 2020
Time of assessment *(00:00-23:59)*	15:48 (24 HR)
Vital Signs Date and Time (derived)	19 AUG 2020 15:48
Temperature *(xxx.x)*	99.3 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	68 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	141 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	92 mmHg
Diastolic Blood Pressure units	MMHG

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US3672203
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Data signed: (b) (4) **15 Feb 2021 20:03:11**
Generated On: 10 Jun 2021 09:23:55

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)*	19 AUG 2020
Time of assessment *(00:00-23:59)*	17:17 (24 HR)
Vital Signs Date and Time (derived)	19 AUG 2020 17:17
Temperature *(xxx.x)*	98.2 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	65 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	81 mmHg
Diastolic Blood Pressure units	MMHG

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US3672203
Folder: Visit 1 Day 1
Form: Physical Examination
Data signed: (b) (4) **15 Feb 2021 20:03:07**
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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.

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US3672203
Folder: Visit 1 Day 1
Form: Exposure
Data signed: (b) (4) **15 Feb 2021 20:03:07**
Generated On: 10 Jun 2021 09:23:55

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)*	19 AUG 2020
What was the treatment time? *(00:00-23:59)*	16:46 (24 HR)
Treatment Date and Time (derived)	19 AUG 2020 16:46
Which arm was used to give treatment?	Left Arm ■ Right Arm ☐
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

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US3672203
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Data signed: (b) (4) **15 Feb 2021 20:03:07**
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Was the sample collected?	Yes ☑ No ☐
Collection date *(dd MMM yyyy)*	19 AUG 2020
Collection time *(00:00-23:59)*	16:08 (24 HR)
Collection date and time (derived)	19 AUG 2020 16:08

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Collection date *(dd MMM yyyy)*			19 AUG 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:38	19 AUG 2020 15:38
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1
Form: Continuing
Data signed: (b) (4) **15 Feb 2021 20:03:07**
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Is the participant continuing to the next visit?	Yes ☑ No ☐
Continuing Flag	1

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US3672203
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:23:55

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.2 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	19 AUG 2020 17:18
PC Open Date & Time	19 AUG 2020 17:06
PC Close Date & Time	19 AUG 2020 19:36

US3672203
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:23:55

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.6 °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 20:32
PC Open Date & Time	19 AUG 2020 20:31
PC Close Date & Time	20 AUG 2020 11:59

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US3672203
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:23:55

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**	98.9 °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	20 AUG 2020 20:46
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

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US3672203
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:23:55

TIMEPOINT	DAY 3

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	98.6 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	21 AUG 2020 12:08
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

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US3672203
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:23:55

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**	98.8 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	22 AUG 2020 18:38
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3672203
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:23:55

TIMEPOINT	DAY 5

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	98.6 °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	23 AUG 2020 16:58
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

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Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:23:55

TIMEPOINT	DAY 6

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	98.9 °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	24 AUG 2020 21:12
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

FDA-CBER-2022-1614-2944306

US3672203
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:23:55

TIMEPOINT	DAY 7

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	98.6 °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	25 AUG 2020 18:10
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

FDA-CBER-2022-1614-2944307

US3672203
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:23:55

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	19 AUG 2020 17:19
PC Open Date & Time	19 AUG 2020 17:06
PC Close Date & Time	19 AUG 2020 19:36

FDA-CBER-2022-1614-2944308

US3672203
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:23:55

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	19 AUG 2020 20:33
PC Open Date & Time	19 AUG 2020 20:31
PC Close Date & Time	20 AUG 2020 11:59

FDA-CBER-2022-1614-2944309

US3672203
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:23:55

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	20 AUG 2020 20:46
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3672203
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:23:55

TIMEPOINT	DAY 3
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ● Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ●
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ●
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ● Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	21 AUG 2020 12:08
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3672203
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:23:55

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	22 AUG 2020 18:38
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3672203
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:23:55

TIMEPOINT	DAY 5
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	23 AUG 2020 16:58
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

FDA-CBER-2022-1614-2944313

US3672203
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:23:55

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 21:13
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3672203
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:23:55

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	25 AUG 2020 18:10
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 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-2022-1614-2944316

US3672203
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:23:55

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	19 AUG 2020 17:19
PC Open Date & Time	19 AUG 2020 17:06
PC Close Date & Time	19 AUG 2020 19:36

FDA-CBER-2022-1614-2944317

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 ☐

US3672203
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:23:55

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	19 AUG 2020 20:34
PC Open Date & Time	19 AUG 2020 20:31
PC Close Date & Time	20 AUG 2020 11:59

FDA-CBER-2022-1614-2944319

US3672203
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:23:55

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-2022-1614-2944320

US3672203
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:23:55

	Yes ☐
PC Time stamp	20 AUG 2020 20:46
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3672203
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:23:55

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-2022-1614-2944322

US3672203
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:23:55

	Yes
PC Time stamp	21 AUG 2020 12:08
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

FDA-CBER-2022-1614-2944323

US3672203
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:23:55

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-2022-1614-2944324

US3672203
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:23:55

	Yes ☐
PC Time stamp	22 AUG 2020 18:38
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3672203
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:23:55

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-2022-1614-2944326

US3672203
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:23:55

	Yes ☐
PC Time stamp	23 AUG 2020 16:58
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3672203
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:23:55

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-2022-1614-2944328

US3672203
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:23:55

	Yes ☐
PC Time stamp	24 AUG 2020 21:13
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3672203
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:23:55

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-2022-1614-2944330

	Yes ☐
PC Time stamp	25 AUG 2020 18:10
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3672203
Folder: Safety Call Day 8 (1)
Form: Safety Call
Data signed: (b) (4) **15 Feb 2021 20:03:07**
Generated On: 10 Jun 2021 09:23:55

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	26 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-2022-1614-2944332

US3672203
Folder: Safety Call Day 8 (1)
Form: Continuing
Data signed: (b) (4) **15 Feb 2021 20:03:07**
Generated On: 10 Jun 2021 09:23:55

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

FDA-CBER-2022-1614-2944333

US3672203
Folder: Safety Call Day 15 (1)
Form: Safety Call
Data signed: (b) (4) **15 Feb 2021 20:03:06**
Generated On: 10 Jun 2021 09:23:55

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	08 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-2022-1614-2944334

US3672203
Folder: Safety Call Day 15 (1)
Form: Continuing
Data signed: (b) (4) **15 Feb 2021 20:03:06**
Generated On: 10 Jun 2021 09:23:55

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

FDA-CBER-2022-1614-2944335

US3672203
Folder: Safety Call Day 22 (1)
Form: Safety Call
Data signed: (b) (4) **15 Feb 2021 20:03:06**
Generated On: 10 Jun 2021 09:23:55

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	11 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-2022-1614-2944336

US3672203
Folder: Safety Call Day 22 (1)
Form: Continuing
Data signed: (b) (4) **15 Feb 2021 20:03:06**
Generated On: 10 Jun 2021 09:23:55

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

FDA-CBER-2022-1614-2944337

US3672203
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Data signed: (b) (4) **15 Feb 2021 20:03:11**
Generated On: 10 Jun 2021 09:23:55

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	18 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	VISIT2

FDA-CBER-2022-1614-2944338

US3672203
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Data signed: (b) (4) **15 Feb 2021 20:03:11**
Generated On: 10 Jun 2021 09:23:55

Timepoint	Pre-Dose ■ Post-Dose ☐
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	18 SEP 2020
Time of assessment *(00:00-23:59)*	12:46 (24 HR)
Vital Signs Date and Time (derived)	18 SEP 2020 12:46
Temperature *(xxx.x)*	98.6 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	74 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	141 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	91 mmHg
Diastolic Blood Pressure units	MMHG

US3672203
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Data signed: (b) (4) **15 Feb 2021 20:03:11**
Generated On: 10 Jun 2021 09:23:55

Timepoint	Pre-Dose ☐ Post-Dose ■
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	18 SEP 2020
Time of assessment *(00:00-23:59)*	14:00 (24 HR)
Vital Signs Date and Time (derived)	18 SEP 2020 14:00
Temperature *(xxx.x)*	98.7 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	70 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	90 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-2944340

US3672203
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Data signed: (b) (4) **15 Feb 2021 20:03:11**
Generated On: 10 Jun 2021 09:23:55

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

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

FDA-CBER-2022-1614-2944341

US3672203
Folder: Visit 2 Day 29 (1)
Form: Exposure
Data signed: (b) (4) **15 Feb 2021 20:03:11**
Generated On: 10 Jun 2021 09:23:55

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 SEP 2020
What was the treatment time? *(00:00-23:59)*	13:29 (24 HR)
Treatment Date and Time (derived)	18 SEP 2020 13:29
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-2022-1614-2944342

US3672203
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **15 Feb 2021 20:03:11**
Generated On: 10 Jun 2021 09:23:55

Was the sample collected?	Yes ☑ No ☐
Collection date *(dd MMM yyyy)*	18 SEP 2020
Collection time *(00:00-23:59)*	13:05 (24 HR)
Collection date and time (derived)	18 SEP 2020 13:05

FDA-CBER-2022-1614-2944343

US3672203
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab
Data signed: (b) (4) **15 Feb 2021 20:03:11**
Generated On: 10 Jun 2021 09:23:55

Collection date *(dd MMM yyyy)*			18 SEP 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:50	18 SEP 2020 12:50
Nasopharyngeal Swab 2	No		

US3672203
Folder: Visit 2 Day 29 (1)
Form: Continuing
Data signed: (b) (4) **15 Feb 2021 20:03:11**
Generated On: 10 Jun 2021 09:23:55

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

FDA-CBER-2022-1614-2944345

US3672203
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:23:55

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**	98.7 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	18 SEP 2020 14:02
PC Open Date & Time	18 SEP 2020 13:49
PC Close Date & Time	18 SEP 2020 16:19

FDA-CBER-2022-1614-2944346

US3672203
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:23:55

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.6 °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	18 SEP 2020 17:24
PC Open Date & Time	18 SEP 2020 17:14
PC Close Date & Time	19 SEP 2020 11:59

FDA-CBER-2022-1614-2944347

US3672203
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:23:55

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**	98.0 °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	19 SEP 2020 18:00
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

FDA-CBER-2022-1614-2944348

US3672203
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:23:55

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**	98.5 °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	20 SEP 2020 19:02
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

FDA-CBER-2022-1614-2944349

US3672203
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:23:55

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**	98.8 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	21 SEP 2020 16:27
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3672203
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:23:55

TIMEPOINT	DAY 5

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	98.9 °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	22 SEP 2020 18:38
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

FDA-CBER-2022-1614-2944351

US3672203
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:23:55

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.

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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	23 SEP 2020 18:56
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

FDA-CBER-2022-1614-2944352

US3672203
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:23:55

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.

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	98.7 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	24 SEP 2020 21:57
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

FDA-CBER-2022-1614-2944353

US3672203
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:23:55

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 SEP 2020 14:02
PC Open Date & Time	18 SEP 2020 13:49
PC Close Date & Time	18 SEP 2020 16:19

FDA-CBER-2022-1614-2944354

US3672203
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:23:55

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 SEP 2020 17:25
PC Open Date & Time	18 SEP 2020 17:14
PC Close Date & Time	19 SEP 2020 11:59

FDA-CBER-2022-1614-2944355

US3672203
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:23:55

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 SEP 2020 17:59
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

FDA-CBER-2022-1614-2944356

US3672203
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:23:55

TIMEPOINT	DAY 3
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	20 SEP 2020 19:02
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3672203
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:23:55

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 SEP 2020 16:27
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3672203
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:23:55

TIMEPOINT	DAY 5
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	22 SEP 2020 18:39
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3672203
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:23:55

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	23 SEP 2020 18:56
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3672203
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:23:55

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 SEP 2020 21:57
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3672203
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:23:55

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-2022-1614-2944362

US3672203
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:23:55

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	18 SEP 2020 14:01
PC Open Date & Time	18 SEP 2020 13:49
PC Close Date & Time	18 SEP 2020 16:19

FDA-CBER-2022-1614-2944363

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 ☐

US3672203
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:23:55

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	18 SEP 2020 17:25
PC Open Date & Time	18 SEP 2020 17:14
PC Close Date & Time	19 SEP 2020 11:59

FDA-CBER-2022-1614-2944365

US3672203
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:23:55

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-2022-1614-2944366

US3672203
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:23:55

	Yes ☐
PC Time stamp	19 SEP 2020 18:00
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3672203
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:23:55

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-2022-1614-2944368

US3672203
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:23:55

	Yes ☐
PC Time stamp	20 SEP 2020 19:02
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3672203
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:23:55

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-2022-1614-2944370

	Yes ☐
PC Time stamp	21 SEP 2020 16:27
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3672203
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:23:55

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-2022-1614-2944372

	Yes ☐
PC Time stamp	22 SEP 2020 18:39
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3672203
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:23:55

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-2022-1614-2944374

US3672203
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:23:55

	Yes ☐
PC Time stamp	23 SEP 2020 18:56
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3672203
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:23:55

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-2022-1614-2944376

US3672203
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:23:55

	Yes ☐
PC Time stamp	24 SEP 2020 21:57
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3672203
Folder: Safety Call Day 36 (1)
Form: Safety Call
Data signed: (b) (4) **15 Feb 2021 20:03:06**
Generated On: 10 Jun 2021 09:23:55

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	28 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-2022-1614-2944378

US3672203
Folder: Safety Call Day 36 (1)
Form: Continuing
Data signed: (b) (4) **15 Feb 2021 20:03:06**
Generated On: 10 Jun 2021 09:23:55

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

FDA-CBER-2022-1614-2944379

US3672203
Folder: Safety Call Day 43 (1)
Form: Safety Call
Data signed: (b) (4) **15 Feb 2021 20:03:07**
Generated On: 10 Jun 2021 09:23:55

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-2022-1614-2944380

US3672203
Folder: Safety Call Day 43 (1)
Form: Continuing
Data signed: (b) (4) **15 Feb 2021 20:03:06**
Generated On: 10 Jun 2021 09:23:55

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

FDA-CBER-2022-1614-2944381

US3672203
Folder: Safety Call Day 50 (1)
Form: Safety Call
Data signed: (b) (4) **15 Feb 2021 20:03:07**
Generated On: 10 Jun 2021 09:23:55

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	12 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-2022-1614-2944382

US3672203
Folder: Safety Call Day 50 (1)
Form: Continuing
Data signed: (b) (4) **15 Feb 2021 20:03:07**
Generated On: 10 Jun 2021 09:23:55

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

FDA-CBER-2022-1614-2944383

US3672203
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Data signed: (b) (4) **15 Feb 2021 20:03:11**
Generated On: 10 Jun 2021 09:23:55

Was this visit performed?	Yes ☑ No ☐
Visit date (dd MMM yyyy)	20 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ☑
Folder OID	VISIT3

FDA-CBER-2022-1614-2944384

US3672203
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Data signed: (b) (4) **15 Feb 2021 20:03:11**
Generated On: 10 Jun 2021 09:23:55

Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	20 OCT 2020
Time of assessment *(00:00-23:59)*	16:55 (24 HR)
Vital Signs Date and Time (derived)	20 OCT 2020 16:55
Temperature *(xxx.x)*	98.6 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	71 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	90 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

FDA-CBER-2022-1614-2944385

US3672203
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Data signed: (b) (4) **15 Feb 2021 20:03:11**
Generated On: 10 Jun 2021 09:23:55

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-2022-1614-2944386

US3672203
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **15 Feb 2021 20:03:11**
Generated On: 10 Jun 2021 09:23:55

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	20 OCT 2020
Collection time *(00:00-23:59)*	17:00 (24 HR)
Collection date and time (derived)	20 OCT 2020 17:00

FDA-CBER-2022-1614-2944387

US3672203
Folder: Visit 3 Day 57 (1)
Form: Continuing
Data signed: (b) (4) **15 Feb 2021 20:03:11**
Generated On: 10 Jun 2021 09:23:55

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

FDA-CBER-2022-1614-2944388

US3672203
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:23:55

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 12:06:58
Patient Cloud Open Date & Time	19 OCT 2020 00:01
Patient Cloud Close Date & Time	23 OCT 2020 23:59

US3672203
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:23:55

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	29 OCT 2020 18:01:05
Patient Cloud Open Date & Time	26 OCT 2020 00:01
Patient Cloud Close Date & Time	30 OCT 2020 23:59

US3672203
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:23:55

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	06 NOV 2020 11:59:24
Patient Cloud Open Date & Time	02 NOV 2020 00:01
Patient Cloud Close Date & Time	06 NOV 2020 23:59

FDA-CBER-2022-1614-2944391

US3672203
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:23:55

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 00:01:58
Patient Cloud Open Date & Time	16 NOV 2020 00:01
Patient Cloud Close Date & Time	20 NOV 2020 23:59

FDA-CBER-2022-1614-2944392

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

FDA-CBER-2022-1614-2944393

US3672203
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:23:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	20 NOV 2020 00:01
Patient Cloud Close Date & Time	24 NOV 2020 23:59

FDA-CBER-2022-1614-2944394

US3672203
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:23:55

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	27 NOV 2020 00:02:05
Patient Cloud Open Date & Time	27 NOV 2020 00:01
Patient Cloud Close Date & Time	01 DEC 2020 23:59

FDA-CBER-2022-1614-2944395

US3672203
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:23:55

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 ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Date and time of submission	04 DEC 2020 00:01:31
Patient Cloud Open Date & Time	04 DEC 2020 00:01
Patient Cloud Close Date & Time	08 DEC 2020 23:59

FDA-CBER-2022-1614-2944396

US3672203
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:23:55

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	11 DEC 2020 00:01:33
Patient Cloud Open Date & Time	11 DEC 2020 00:01
Patient Cloud Close Date & Time	15 DEC 2020 23:59

FDA-CBER-2022-1614-2944397

US3672203
Folder: Cosmetic Injections and Dermal Fillers
Form: Cosmetic Injection_ Dermal Filler eDiary
Generated On: 10 Jun 2021 09:23:55

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission

FDA-CBER-2022-1614-2944398

US3672203
Folder: Safety Call Day 85 (1)
Form: Safety Call
Data signed: (b) (4) **05 Mar 2021 17:41:49**
Generated On: 10 Jun 2021 09:23:55

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	14 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-2022-1614-2944399

US3672203
Folder: Safety Call Day 85 (1)
Form: Continuing
Data signed: (b) (4) **05 Mar 2021 17:41:49**
Generated On: 10 Jun 2021 09:23:55

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

FDA-CBER-2022-1614-2944400

US3672203
Folder: Safety Call Day 119 (1)
Form: Safety Call
Data signed: (b) (4) **05 Mar 2021 17:41:49**
Generated On: 10 Jun 2021 09:23:55

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	11 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-2022-1614-2944401

US3672203
Folder: Safety Call Day 119 (1)
Form: Continuing
Data signed: (b) (4) **05 Mar 2021 17:41:49**
Generated On: 10 Jun 2021 09:23:55

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

FDA-CBER-2022-1614-2944402

US3672203
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:23:55

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

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

US3672203
Folder: Covid-19 Assessment (1)
Form: COVID-19 Contact
Generated On: 10 Jun 2021 09:23:55

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-2022-1614-2944405

Generate Next COVID-19 Assessment	Yes ☐ No ☐

US3672203
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:23:55

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

FDA-CBER-2022-1614-2944407

US3672203
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 09:23:55

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

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

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

US3672203
Folder: Adverse Events
Form: Adverse Events Summary
Data signed: (b) (4) **05 Mar 2021 17:41:48**
Generated On: 10 Jun 2021 09:23:55

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

If Yes, enter details on the Adverse Events form.

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US3672203
Folder: Adverse Events
Form: Adverse Events (1)
Data signed: (b) (4) **05 Mar 2021 17:41:48**
Generated On: 10 Jun 2021 09:23:55

AEID	USA-US116-2021-MRNA-1273-P30 1000003
Adverse event	COMMITTED SUICIDE
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)*	13 DEC 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ■
If not Ongoing, end date *(dd MMM yyyy)*	13 DEC 2020
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ■
Is the adverse event serious?	Yes ■ No ☐
AE is serious due To (check all that apply)	
Death	True
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐

US3672203
Folder: Adverse Events
Form: Adverse Events (1)
Data signed: (b) (4) **05 Mar 2021 17:41:48**
Generated On: 10 Jun 2021 09:23:55

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	SITE STAFF SPOKE TO SUBJECT'S MOTHER REGARDING PARTICIPATION IN STUDY AND SHE HAD INFORMED US THAT HER SON HAD COMMITTED SUICIDE ON 12/13/2020.

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US3672203
Folder: Adverse Events
Form: Adverse Events (1)
Data signed: (b) (4) **05 Mar 2021 17:41:48**
Generated On: 10 Jun 2021 09:23:55

Serious Adverse Event Derived (CSA Programming Field Ony)	1
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3672203
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination Summary
Data signed: (b) (4) **05 Mar 2021 17:41:48**
Generated On: 10 Jun 2021 09:23:55

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

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

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US3672203
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Data signed: (b) (4) **05 Mar 2021 17:41:48**
Generated On: 10 Jun 2021 09:23:55

Name of Medication	LEXAPRO
Prophylaxis	Yes ☐ No ■
Indication	ANXIETY
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 ☐

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

US3672203
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures Summary
Data signed: (b) (4) **05 Mar 2021 17:41:48**
Generated On: 10 Jun 2021 09:23:55

Were any concomitant procedures performed?	Yes ☐
	No ■

If yes, please complete Concomitant Procedures form.

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

US3672203
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Data signed: (b) (4) **20 Apr 2021 15:32:48**
Generated On: 10 Jun 2021 09:23:55

Date of study discontinuation/completion *(dd MMM yyyy)*	13 DEC 2020
Reason for discontinuation	AE (specify) ☐ SAE (specify) ☐ Complete ☐ Death ■ Lost To Follow-up ☐ Physician decision (specify) ☐ Pregnancy ☐ Protocol deviation (specify) ☐ Study Terminated By Sponsor ☐ Withdrawal of consent by participant (specify) ☐ Other ☐
If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify	
If reason for discontinuation is Death, main cause of death	Adverse event ■ Unknown ☐ Other ☐
If main cause of death is Other, specify	
Date of death *(dd MMM yyyy)*	13 DEC 2020
Was autopsy performed?	Yes ☐ No ☐ Unknown ■

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US3672203
Folder: SAE USA-US116-2021-MRNA-1273-P301000003
Form: Safety Report Form
Data signed: (b) (4) **05 Mar 2021 17:41:48**
Generated On: 10 Jun 2021 09:23:55

SAEID	USA-US116-2021-MRNA-1273-P301000003
Serious	Yes ■ No ☐
Death	Yes ■ No ☐
Life threatening	Yes ☐ No ■
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ■
Persistent or significant disability or incapacity	Yes ☐ No ■
Congenital anomaly or birth defect	Yes ☐ No ■
Other medically important event	Yes ☐ No ■
Investigator's First Name	CYNTHIA
Investigator's Last Name	STROUT
Site Address: Street	4920 O HEAR AVE SUITE 101
Site Address: City	NORTH CHARLESTON
Site Address: State	SC
Site Address: Postal Code	29405
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1

US3672203
Folder: SAE USA-US116-2021-MRNA-1273-P301000003
Form: Safety Report Form (1)
Data signed: (b) (4) **05 Mar 2021 17:41:48**
Generated On: 10 Jun 2021 09:23:55

SAEID	USA-US116-2021-MRNA-1273-P301000003
Serious	Yes ■ No ☐
Death	Yes ■ No ☐
Life threatening	Yes ☐ No ■
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ■
Persistent or significant disability or incapacity	Yes ☐ No ■
Congenital anomaly or birth defect	Yes ☐ No ■
Other medically important event	Yes ☐ No ■
Investigator's First Name	CYNTHIA
Investigator's Last Name	STROUT
Site Address: Street	4920 O HEAR AVE SUITE 101
Site Address: City	NORTH CHARLESTON
Site Address: State	SC
Site Address: Postal Code	29405
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1
Date of submission (Pre-filled from custom function)	21/JAN/2021 13:22
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3672203
Form: Participant Creation
Generated On: 10 Jun 2021 09:23:55
Participant ID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:49
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:06:51
User entered 'US3672203'	RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 19:44:34

US3672203
Form: Participant Creation
Generated On: 10 Jun 2021 09:23:55

mRNA-1273-P301 Completion Guidelines

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18

FDA-CBER-2022-1614-2944425

US3672203
Folder: Screening
Form: Visit Date
Generated On: 10 Jun 2021 09:23:55
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:42:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 20:20:47

FDA-CBER-2022-1614-2944426

US3672203
Folder: Screening
Form: Visit Date
Generated On: 10 Jun 2021 09:23:55
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:42:06
User entered '19 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 19:44:35

FDA-CBER-2022-1614-2944427

US3672203
Folder: Screening
Form: Visit Date
Generated On: 10 Jun 2021 09:23:55
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 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:42:06
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	19 Aug 2020 20:20:47

US3672203
Folder: Screening
Form: Visit Date
Generated On: 10 Jun 2021 09:23:55
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User entered 'SCRN'	System	19 Aug 2020 20:20:47

US3672203
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:23:55
Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:42:10
User entered (b) (6) 1995'	RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 19:44:36

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US3672203
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:23:55
Age

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:42:10
User entered '25'	(b) (4), (b) (6)	19 Aug 2020 20:21:14

FDA-CBER-2022-1614-2944431

US3672203
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:23:55
Age Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User entered 'YEARS'	System	19 Aug 2020 20:21:14

FDA-CBER-2022-1614-2944432

US3672203
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:23:55
Age (Derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User entered '25'	System	19 Aug 2020 20:21:26

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US3672203
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:23:55
Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:42:10
User entered 'Male (M)'	(b) (4), (b) (6)	19 Aug 2020 20:21:14

US3672203
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:23:55
Ethnicity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:42:10
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	19 Aug 2020 20:21:14

US3672203
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:23:55
White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:42:10
User entered '1'	(b) (4), (b) (6)	19 Aug 2020 20:21:14

FDA-CBER-2022-1614-2944436

US3672203
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:23:55
Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:42:10
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 20:21:14

US3672203
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:23:55
Asian

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:42:10
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 20:21:14

FDA-CBER-2022-1614-2944438

US3672203
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:23:55
American Indian or Alaska Native

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:42:10
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 20:21:14

US3672203
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:23:55
Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:42:10
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 20:21:14

US3672203
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:23:55
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:42:10
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 20:21:14

FDA-CBER-2022-1614-2944441

US3672203
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:23:55
If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:42:10
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 20:21:14

FDA-CBER-2022-1614-2944442

US3672203
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:23:55
Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:42:10
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 20:21:14

FDA-CBER-2022-1614-2944443

US3672203
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:23:55
Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:42:10
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 20:21:14

FDA-CBER-2022-1614-2944444

US3672203
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 09:23:55
Date of Informed Consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:43:07
User entered '19 Aug 2020'	(b) (4), (b) (6)	19 Aug 2020 20:21:26

FDA-CBER-2022-1614-2944445

US3672203
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 09:23:55
Month and Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User entered 'Aug 2020'	System	19 Aug 2020 20:21:26

FDA-CBER-2022-1614-2944446

US3672203
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 09:23:55
Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User entered '2020'	System	19 Aug 2020 20:21:26

FDA-CBER-2022-1614-2944447

US3672203
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 09:23:55
Protocol Version

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:43:07
User entered 'Amendment 2 (2)'	(b) (4), (b) (6)	19 Aug 2020 20:21:26

FDA-CBER-2022-1614-2944448

US3672203
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 09:23:55
Was participant enrolled in the study?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:43:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 20:21:26

FDA-CBER-2022-1614-2944449

US3672203
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 09:23:55
If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:43:07
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 20:21:26

FDA-CBER-2022-1614-2944450

US3672203
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 09:23:55
If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:43:07
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 20:21:26

FDA-CBER-2022-1614-2944451

US3672203
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 09:23:55
Was this participant screened previously?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:43:07
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 20:21:26

FDA-CBER-2022-1614-2944452

US3672203
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 09:23:55
If Yes, previous participant number

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:43:07
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 19:44:35

FDA-CBER-2022-1614-2944453

US3672203
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 09:23:55
Enrollment Trigger

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User entered '1'	System	19 Aug 2020 20:21:43

US3672203
Folder: Screening
Form: Inclusion/Exclusion Criteria Summary
Generated On: 10 Jun 2021 09:23:55
Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:43:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 20:21:43

FDA-CBER-2022-1614-2944455

US3672203
Folder: Screening
Form: Medical History Summary
Generated On: 10 Jun 2021 09:23:55
Were any significant conditions reported?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:43:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 14:53:00

FDA-CBER-2022-1614-2944456

US3672203
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 09:23:55
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:43:23
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Aug 2020 14:55:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Aug 2020 14:55:16
Data point term sent to Coder	System	21 Aug 2020 14:53:46
User entered 'anxiety'	(b) (4), (b) (6)	21 Aug 2020 14:53:45

FDA-CBER-2022-1614-2944457

US3672203
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 09:23:55
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:43:23
User entered 'un Jan 2020'	(b) (4), (b) (6)	21 Aug 2020 14:53:45

FDA-CBER-2022-1614-2944458

US3672203
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 09:23:55
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:43:23
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 14:53:45

FDA-CBER-2022-1614-2944459

US3672203
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 09:23:55
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:43:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 14:53:45

FDA-CBER-2022-1614-2944460

US3672203
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 09:23:55
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:43:23
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 14:53:45

FDA-CBER-2022-1614-2944461

US3672203
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 09:23:55
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:43:23
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 14:53:45

FDA-CBER-2022-1614-2944462

US3672203
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 09:23:55
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User entered 'Jan 2020'	System	21 Aug 2020 14:53:45

FDA-CBER-2022-1614-2944463

US3672203
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 09:23:55
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User entered '2020'	System	21 Aug 2020 14:53:45

FDA-CBER-2022-1614-2944464

US3672203
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 09:23:55
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User entered empty.	System	21 Aug 2020 14:53:45

FDA-CBER-2022-1614-2944465

US3672203
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 09:23:55
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User entered empty.	System	21 Aug 2020 14:53:45

FDA-CBER-2022-1614-2944466

US3672203
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 09:23:55
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:43:23
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Allergy to antibiotic - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Aug 2020 14:55:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Aug 2020 14:55:17
Data point term sent to Coder	System	21 Aug 2020 14:54:47
User entered 'amoxicillin allergy'	(b) (4), (b) (6)	21 Aug 2020 14:54:00

US3672203
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 09:23:55
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:43:23
User entered 'un UNK 2000'	(b) (4), (b) (6)	21 Aug 2020 14:54:00

FDA-CBER-2022-1614-2944468

US3672203
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 09:23:55
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:43:23
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 14:54:00

FDA-CBER-2022-1614-2944469

US3672203
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 09:23:55
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:43:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 14:54:00

US3672203
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 09:23:55
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:43:23
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 14:54:00

FDA-CBER-2022-1614-2944471

US3672203
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 09:23:55
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:43:23
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 14:54:00

FDA-CBER-2022-1614-2944472

US3672203
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 09:23:55
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User entered 'Jan 2000'	System	21 Aug 2020 14:54:00

FDA-CBER-2022-1614-2944473

US3672203
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 09:23:55
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User entered '2000'	System	21 Aug 2020 14:54:00

FDA-CBER-2022-1614-2944474

US3672203
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 09:23:55
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User entered empty.	System	21 Aug 2020 14:54:00

FDA-CBER-2022-1614-2944475

US3672203
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 09:23:55
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User entered empty.	System	21 Aug 2020 14:54:00

FDA-CBER-2022-1614-2944476

US3672203
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:23:55
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:44:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 14:54:27

US3672203
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:23:55
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:44:05
User closed query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	21 Aug 2020 14:54:37
Query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	21 Aug 2020 14:54:37
User closed query 'Screening Vital Signs is not within 28 days of Visit 1. Please reconcile or confirm dates.' (Site from System).	System	21 Aug 2020 14:54:37
Query 'Screening Vital Signs is not within 28 days of Visit 1. Please reconcile or confirm dates.' answered by data change (Site from System).	System	21 Aug 2020 14:54:37
User entered '19 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 14:54:37
User opened query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	21 Aug 2020 14:54:27
User opened query 'Screening Vital Signs is not within 28 days of Visit 1. Please reconcile or confirm dates.' (Site from System).	System	21 Aug 2020 14:54:27
User entered '21 Aug 2020'	(b) (4), (b) (6)	21 Aug 2020 14:54:27

FDA-CBER-2022-1614-2944478

US3672203
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:23:55
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:44:05
User entered '15:48'	(b) (4), (b) (6)	21 Aug 2020 14:54:27

FDA-CBER-2022-1614-2944479

US3672203
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:23:55
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User entered '19 Aug 2020 15:48'	System	21 Aug 2020 14:54:37
User entered '21 Aug 2020 15:48'	System	21 Aug 2020 14:54:27

US3672203
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:23:55
Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:44:05
User entered '177.5' cm	(b) (4), (b) (6)	21 Aug 2020 14:54:27
DataPoint set to visible.	System	19 Aug 2020 20:21:43

US3672203
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:23:55
Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:44:05
User entered '62.9' kg	(b) (4), (b) (6)	21 Aug 2020 14:54:27
DataPoint set to visible.	System	19 Aug 2020 20:21:43

FDA-CBER-2022-1614-2944482

US3672203
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:23:55
BMI *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
Amendment Manager: User entered '19.96429'	System	17 Sep 2020 00:14:53
User entered '20.0'	System	21 Aug 2020 14:54:27
DataPoint set to visible.	System	19 Aug 2020 20:21:43

FDA-CBER-2022-1614-2944483

US3672203
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:23:55
BMI units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User entered 'kg/m2'	System	21 Aug 2020 14:54:27
DataPoint set to visible.	System	19 Aug 2020 20:21:43

US3672203
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:23:55
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:07:04
User closed query 'Per CDM: Response noted; however, per CCGs pages 15-16, “ND” should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 11:48:23
Query 'Per CDM: Response noted; however, per CCGs pages 15-16, “ND” should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 19:08:14
DataPoint Un-verified.	(b) (4), (b) (6)	23 Sep 2020 19:08:07
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	23 Sep 2020 19:08:07
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:44:05
Query 'Data is required. Please provide.' canceled (Site from System).	(b) (4), (b) (6)	24 Aug 2020 14:56:16
User opened query 'Per CDM: Response noted; however, per CCGs pages 15-16, “ND” should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	24 Aug 2020 14:56:14
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Aug 2020 14:54:27
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 14:54:27

US3672203
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:23:55
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:44:05
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 14:54:27

FDA-CBER-2022-1614-2944486

US3672203
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:23:55
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:44:05
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 14:54:27

FDA-CBER-2022-1614-2944487

US3672203
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:23:55
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:07:04
DataPoint Un-verified.	(b) (4), (b) (6)	23 Sep 2020 19:08:07
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	23 Sep 2020 19:08:07
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:44:05
Query 'Data is required. Please provide.' canceled (Site from System).	(b) (4), (b) (6)	24 Aug 2020 14:56:18
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Aug 2020 14:54:27
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 14:54:27

US3672203
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:23:55
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User entered 'bpm'	System	23 Sep 2020 19:08:07
User entered empty.	System	21 Aug 2020 14:54:27

US3672203
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:23:55
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:07:04
DataPoint Un-verified.	(b) (4), (b) (6)	23 Sep 2020 19:08:07
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	23 Sep 2020 19:08:07
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:44:05
Query 'Data is required. Please provide.' canceled (Site from System).	(b) (4), (b) (6)	24 Aug 2020 14:56:21
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Aug 2020 14:54:27
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 14:54:27

FDA-CBER-2022-1614-2944490

US3672203
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:23:55
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User entered 'breaths/min'	System	23 Sep 2020 19:08:07
User entered empty.	System	21 Aug 2020 14:54:27

US3672203
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:23:55
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:07:04
DataPoint Un-verified.	(b) (4), (b) (6)	23 Sep 2020 19:08:07
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	23 Sep 2020 19:08:07
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:44:05
Query 'Data is required. Please provide.' canceled (Site from System).	(b) (4), (b) (6)	24 Aug 2020 14:56:22
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Aug 2020 14:54:27
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 14:54:27

FDA-CBER-2022-1614-2944492

US3672203
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:23:55
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User entered 'mmHg'	System	23 Sep 2020 19:08:07
User entered empty.	System	21 Aug 2020 14:54:27

US3672203
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:23:55
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:07:04
DataPoint Un-verified.	(b) (4), (b) (6)	23 Sep 2020 19:08:07
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	23 Sep 2020 19:08:07
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:44:05
Query 'Data is required. Please provide.' canceled (Site from System).	(b) (4), (b) (6)	24 Aug 2020 14:56:24
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Aug 2020 14:54:27
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 14:54:27

US3672203
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:23:55
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User entered 'mmHg'	System	23 Sep 2020 19:08:07
User entered empty.	System	21 Aug 2020 14:54:27

US3672203
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:23:55
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18

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US3672203
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:23:55
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18

FDA-CBER-2022-1614-2944497

US3672203
Folder: Screening
Form: Physical Examination
Generated On: 10 Jun 2021 09:23:55
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:44:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 14:54:49

US3672203
Folder: Screening
Form: Physical Examination
Generated On: 10 Jun 2021 09:23:55
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:44:15
User entered '19 Aug 2020'	(b) (4), (b) (6)	21 Aug 2020 14:54:49

US3672203
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:23:55
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 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:44:25
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 14:55:47

US3672203
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:23:55
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 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:44:25
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 14:55:47

US3672203
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:23:55
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 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:44:25
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 14:55:47

US3672203
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:23:55
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 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:44:25
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 14:55:47

US3672203
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:23:55
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 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:44:25
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 14:55:47

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US3672203
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:23:55
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 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:44:25
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 14:55:47

US3672203
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:23:55
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 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:44:25
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 14:55:47

US3672203
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:23:55
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 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:44:25
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 14:55:47

US3672203
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:23:55
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 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:44:25
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 14:55:47

US3672203
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:23:55
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 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:44:25
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 14:55:47

US3672203
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:23:55
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 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:44:25
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 14:55:47

US3672203
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:23:55
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:44:25
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 14:55:47

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US3672203
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:23:55
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:44:25
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 14:55:47

US3672203
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:23:55
No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:03:07
User entered '0'	(b) (4), (b) (6) (b) (4)	21 Aug 2020 14:55:47

US3672203
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:23:55
Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:44:25
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 14:55:47

US3672203
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:23:55
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 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:44:25
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 14:55:47

US3672203
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:23:55
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 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:44:25
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 14:55:47

US3672203
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:23:55
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 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:44:25
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 14:55:47

US3672203
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:23:55
Resides in a single family home (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:44:25
User entered '1'	(b) (4), (b) (6)	21 Aug 2020 14:55:47

US3672203
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:23:55
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:03:07
User entered '1'	(b) (4), (b) (6)	21 Aug 2020 14:55:47

US3672203
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:23:55
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:44:25
User entered 'resident in a community with ongoing person to person transmission'	(b) (4), (b) (6)	21 Aug 2020 14:55:47

US3672203
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 10 Jun 2021 09:23:55
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:11
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:44:33
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 20:22:10

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US3672203
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 10 Jun 2021 09:23:55
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:11
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:44:33
User entered '19 Aug 2020'	(b) (4), (b) (6)	19 Aug 2020 20:22:10

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US3672203
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 10 Jun 2021 09:23:55
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 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:11
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:44:33
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	19 Aug 2020 20:22:10

US3672203
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 10 Jun 2021 09:23:55
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User entered 'VISIT1'	System	19 Aug 2020 20:22:10

FDA-CBER-2022-1614-2944524

US3672203
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 09:23:55
What was the date of randomization? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:11
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:44:37
User entered '19 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 20:24:38

FDA-CBER-2022-1614-2944525

US3672203
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 09:23:55
What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:11
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:44:37
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 05:42:02
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 05:42:02
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	19 Aug 2020 20:24:38
User entered '106157' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 20:24:38

US3672203
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 09:23:55
In what Cohort was the participant enrolled?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:03:11
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:44:37
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 20:24:38

FDA-CBER-2022-1614-2944527

US3672203
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 09:23:55
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)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:11
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:44:37
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 20:23:01

US3672203
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 09:23:55
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)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:11
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:44:37
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 20:23:01

US3672203
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 09:23:55
Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:11
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:44:37
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 20:23:01

FDA-CBER-2022-1614-2944530

US3672203
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 09:23:55
Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:11
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:44:37
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 20:23:01

FDA-CBER-2022-1614-2944531

US3672203
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 09:23:55
Liver Disease

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:11
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:44:37
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 20:23:01

FDA-CBER-2022-1614-2944532

US3672203
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 09:23:55
Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:36:15
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 01:37:07

FDA-CBER-2022-1614-2944533

US3672203
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 09:23:55
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:03:11
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:07:18
User closed query 'Per CDM: Response noted; however, per CCGs pages 15-16, "ND" should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 07:33:18
Query 'Per CDM: Response noted; however, per CCGs pages 15-16, "ND" should be recorded for HEIGHT and WEIGHT. Please update accordingly.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 19:08:31
DataPoint Un-verified.	(b) (4), (b) (6)	23 Sep 2020 19:08:25
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	23 Sep 2020 19:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:44:42
User opened query 'Per CDM: Response noted; however, per CCGs pages 15-16, "ND" should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	24 Aug 2020 14:55:01
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 14:57:29

US3672203
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 09:23:55
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:03:11
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:07:18
DataPoint Un-verified.	(b) (4), (b) (6)	23 Sep 2020 19:08:25
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	23 Sep 2020 19:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:44:42
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 14:57:29

US3672203
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 09:23:55
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:03:11
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:07:18
User closed query 'Per CDM: Response noted; however, per CCGs pages 15-16, "ND" should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 07:33:18
Query 'Per CDM: Response noted; however, per CCGs pages 15-16, "ND" should be recorded for HEIGHT and WEIGHT. Please update accordingly.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 19:08:31
DataPoint Un-verified.	(b) (4), (b) (6)	23 Sep 2020 19:08:25
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	23 Sep 2020 19:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:44:42
User opened query 'Per CDM: Response noted; however, per CCGs pages 15-16, "ND" should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	24 Aug 2020 14:55:01
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 14:57:29

US3672203
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 09:23:55
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:11
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:07:18
DataPoint Un-verified.	(b) (4), (b) (6)	23 Sep 2020 19:08:25
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	23 Sep 2020 19:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:44:42
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 14:57:29

US3672203
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:23:55
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	21 Aug 2020 14:57:29

US3672203
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:23:55
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:11
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:44:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 14:57:29

FDA-CBER-2022-1614-2944539

US3672203
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:23:55
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:11
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:44:42
User entered '19 Aug 2020'	(b) (4), (b) (6)	21 Aug 2020 14:57:29

FDA-CBER-2022-1614-2944540

US3672203
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:23:55
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:11
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:44:42
User entered '15:48'	(b) (4), (b) (6)	21 Aug 2020 14:57:29

FDA-CBER-2022-1614-2944541

US3672203
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:23:55
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User entered '19 Aug 2020 15:48'	System	21 Aug 2020 14:57:29

US3672203
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:23:55
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:03:11
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:44:42
User entered '99.3' F	(b) (4), (b) (6)	21 Aug 2020 14:57:29

US3672203
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:23:55
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:11
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:44:42
User entered 'Oral (Oral)'	(b) (4), (b) (6)	21 Aug 2020 14:57:29

FDA-CBER-2022-1614-2944544

US3672203
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:23:55
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:11
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:44:42
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 14:57:29

FDA-CBER-2022-1614-2944545

US3672203
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:23:55
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:11
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:44:42
User entered '68'	(b) (4), (b) (6)	21 Aug 2020 14:57:29

FDA-CBER-2022-1614-2944546

US3672203
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:23:55
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User entered 'bpm'	System	21 Aug 2020 14:57:29

FDA-CBER-2022-1614-2944547

US3672203
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:23:55
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:11
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:44:42
User entered '16'	(b) (4), (b) (6)	21 Aug 2020 14:57:29

FDA-CBER-2022-1614-2944548

US3672203
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:23:55
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User entered 'breaths/min'	System	21 Aug 2020 14:57:29

US3672203
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:23:55
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:03:11
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:44:42
User entered '141'	(b) (4), (b) (6)	21 Aug 2020 14:57:29

US3672203
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:23:55
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User entered 'mmHg'	System	21 Aug 2020 14:57:29

FDA-CBER-2022-1614-2944551

US3672203
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:23:55
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:11
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:44:42
User entered '92'	(b) (4), (b) (6)	21 Aug 2020 14:57:29

US3672203
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:23:55
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User entered 'mmHg'	System	21 Aug 2020 14:57:29

US3672203
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 09:23:55
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:03:11
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:07:18
User closed query 'Per CDM: Response noted; however, per CCGs pages 15-16, "ND" should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 07:33:18
Query 'Per CDM: Response noted; however, per CCGs pages 15-16, "ND" should be recorded for HEIGHT and WEIGHT. Please update accordingly.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 19:08:31
DataPoint Un-verified.	(b) (4), (b) (6)	23 Sep 2020 19:08:25
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	23 Sep 2020 19:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:44:42
User opened query 'Per CDM: Response noted; however, per CCGs pages 15-16, "ND" should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	24 Aug 2020 14:55:01
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 14:57:29

US3672203
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 09:23:55
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:11
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:07:18
DataPoint Un-verified.	(b) (4), (b) (6)	23 Sep 2020 19:08:25
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	23 Sep 2020 19:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:44:42
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 14:57:29

US3672203
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:23:55
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	21 Aug 2020 14:57:29

US3672203
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:23:55
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:11
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:07:18
User closed query 'Response to were vital signs assessed is No, but data is provided below. Please correct.' (Site from System).	System	23 Sep 2020 19:08:51
DataPoint Un-verified.	(b) (4), (b) (6)	23 Sep 2020 19:08:51
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Sep 2020 19:08:51
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:44:42
User opened query 'Response to were vital signs assessed is No, but data is provided below. Please correct.' (Site from System).	System	21 Aug 2020 14:57:29
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 14:57:29

US3672203
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:23:55
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:11
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:44:42
User entered '19 Aug 2020'	(b) (4), (b) (6)	21 Aug 2020 14:57:29

FDA-CBER-2022-1614-2944558

US3672203
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:23:55
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:11
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:44:42
User entered '17:17'	(b) (4), (b) (6)	21 Aug 2020 14:57:29

FDA-CBER-2022-1614-2944559

US3672203
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:23:55
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User entered '19 Aug 2020 17:17'	System	21 Aug 2020 14:57:29

US3672203
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:23:55
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:11
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:44:42
User entered '98.2' F	(b) (4), (b) (6)	21 Aug 2020 14:57:29

US3672203
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:23:55
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:11
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:44:42
User entered 'Oral (Oral)'	(b) (4), (b) (6)	21 Aug 2020 14:57:29

FDA-CBER-2022-1614-2944562

US3672203
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:23:55
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:11
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:44:42
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 14:57:29

US3672203
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:23:55
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:11
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:44:42
User entered '65'	(b) (4), (b) (6)	21 Aug 2020 14:57:29

US3672203
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:23:55
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User entered 'bpm'	System	21 Aug 2020 14:57:29

US3672203
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:23:55
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:11
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:44:42
User entered '16'	(b) (4), (b) (6)	21 Aug 2020 14:57:29

FDA-CBER-2022-1614-2944566

US3672203
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:23:55
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User entered 'breaths/min'	System	21 Aug 2020 14:57:29

US3672203
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:23:55
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:03:11
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:44:42
User entered '129'	(b) (4), (b) (6)	21 Aug 2020 14:57:29

FDA-CBER-2022-1614-2944568

US3672203
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:23:55
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User entered 'mmHg'	System	21 Aug 2020 14:57:29

FDA-CBER-2022-1614-2944569

US3672203
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:23:55
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:11
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:44:42
User entered '81'	(b) (4), (b) (6)	21 Aug 2020 14:57:29

US3672203
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:23:55
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User entered 'mmHg'	System	21 Aug 2020 14:57:29

FDA-CBER-2022-1614-2944571

US3672203
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 10 Jun 2021 09:23:55
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:45:00
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 21:01:04

FDA-CBER-2022-1614-2944572

US3672203
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 10 Jun 2021 09:23:55
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:45:00
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 21:01:04

FDA-CBER-2022-1614-2944573

US3672203
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:23:55
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:45:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 20:49:04

FDA-CBER-2022-1614-2944574

US3672203
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:23:55
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:45:32
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 20:49:04

FDA-CBER-2022-1614-2944575

US3672203
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:23:55
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)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:45:32
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 20:49:04

US3672203
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:23:55
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User entered 'MRNA-1273 OR PLACEBO'	System	19 Aug 2020 20:49:04

US3672203
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:23:55
What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:45:32
User entered '19 Aug 2020'	(b) (4), (b) (6)	19 Aug 2020 20:49:04

FDA-CBER-2022-1614-2944578

US3672203
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:23:55
What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:45:32
User entered '16:46'	(b) (4), (b) (6)	19 Aug 2020 20:49:04

FDA-CBER-2022-1614-2944579

US3672203
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:23:55
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User entered '19 Aug 2020 16:46'	System	19 Aug 2020 20:49:04

US3672203
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:23:55
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:45:32
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	19 Aug 2020 20:49:04

FDA-CBER-2022-1614-2944581

US3672203
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:23:55
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:45:32
User entered 'ONCE'	System	19 Aug 2020 20:49:04

US3672203
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:23:55
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User entered 'INTRAMUSCULAR'	System	19 Aug 2020 20:49:04

US3672203
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:23:55
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:45:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 14:58:04

FDA-CBER-2022-1614-2944584

US3672203
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:23:55
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:45:37
User entered '19 Aug 2020'	(b) (4), (b) (6)	21 Aug 2020 14:58:04

FDA-CBER-2022-1614-2944585

US3672203
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:23:55
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:45:37
User entered '16:08'	(b) (4), (b) (6)	21 Aug 2020 14:58:04

FDA-CBER-2022-1614-2944586

US3672203
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:23:55
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User entered '19 Aug 2020 16:08'	System	21 Aug 2020 14:58:04

FDA-CBER-2022-1614-2944587

US3672203
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab
Generated On: 10 Jun 2021 09:23:55
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:45:49
User entered '19 Aug 2020'	(b) (4), (b) (6)	21 Aug 2020 14:58:20

FDA-CBER-2022-1614-2944588

US3672203
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 09:23:55
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	21 Aug 2020 14:58:20

US3672203
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 09:23:55
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:45:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 14:58:20

US3672203
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 09:23:55
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:45:49
User entered '15:38'	(b) (4), (b) (6)	21 Aug 2020 14:58:20

US3672203
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 09:23:55
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User entered '19 Aug 2020 15:38'	System	21 Aug 2020 14:58:20

US3672203
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 09:23:55
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	21 Aug 2020 14:58:20

US3672203
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 09:23:55
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:45:49
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 14:58:20

US3672203
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 09:23:55
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:45:49
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 14:58:20

US3672203
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 09:23:55
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User entered empty.	System	21 Aug 2020 14:58:20

US3672203
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 10 Jun 2021 09:23:55
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:45:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 14:58:28

FDA-CBER-2022-1614-2944597

US3672203
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 10 Jun 2021 09:23:55
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User entered '1'	System	21 Aug 2020 14:58:28

FDA-CBER-2022-1614-2944598

US3672203
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:23:55
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
Data entry locked.	System	19 Aug 2020 20:49:04
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Aug 2020 20:49:04

US3672203
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:23:55
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-19T17:17:47', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '4da65e3b-cd20-4ab7-b082-ebbdcddff0c5'	System	19 Aug 2020 21:18:42
User entered 'Yes (Y)'	System	19 Aug 2020 21:18:42

FDA-CBER-2022-1614-2944600

US3672203
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:23:55
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-19T17:18:19', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '4da65e3b-cd20-4ab7-b082-ebbdcddff0c5'	System	19 Aug 2020 21:18:42
User entered '98.2'	System	19 Aug 2020 21:18:42

FDA-CBER-2022-1614-2944601

US3672203
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:23:55
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-19T17:18:32', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '4da65e3b-cd20-4ab7-b082-ebbdcddff0c5'	System	19 Aug 2020 21:18:42
User entered 'No (N)'	System	19 Aug 2020 21:18:42

FDA-CBER-2022-1614-2944602

US3672203
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:23:55
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-19T17:18:39', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '4da65e3b-cd20-4ab7-b082-ebbdcddff0c5'	System	19 Aug 2020 21:18:42
User entered '19 Aug 2020 17:18'	System	19 Aug 2020 21:18:42

FDA-CBER-2022-1614-2944603

US3672203
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:23:55
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
User entered '19 Aug 2020 17:06'	System	19 Aug 2020 20:49:04

FDA-CBER-2022-1614-2944604

US3672203
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:23:55
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
User entered '19 Aug 2020 19:36'	System	19 Aug 2020 20:49:04

FDA-CBER-2022-1614-2944605

US3672203
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:23:55
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
Data entry locked.	System	19 Aug 2020 20:49:04
User entered 'Day 1, after vaccination (at home)'	System	19 Aug 2020 20:49:04

US3672203
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:23:55
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-19T20:32:27', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: 'a6dbb25b-2e7b-4201-aba2-35294fc43491'	System	20 Aug 2020 00:32:46
User entered 'Yes (Y)'	System	20 Aug 2020 00:32:46

FDA-CBER-2022-1614-2944607

US3672203
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:23:55
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-19T20:32:33', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: 'a6dbb25b-2e7b-4201-aba2-35294fc43491'	System	20 Aug 2020 00:32:46
User entered '98.6'	System	20 Aug 2020 00:32:46

FDA-CBER-2022-1614-2944608

US3672203
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:23:55
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-19T20:32:37', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: 'a6dbb25b-2e7b-4201-aba2-35294fc43491'	System	20 Aug 2020 00:32:46
User entered 'No (N)'	System	20 Aug 2020 00:32:46

FDA-CBER-2022-1614-2944609

US3672203
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:23:55
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-19T20:32:42', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: 'a6dbb25b-2e7b-4201-aba2-35294fc43491'	System	20 Aug 2020 00:32:46
User entered '19 Aug 2020 20:32'	System	20 Aug 2020 00:32:46

FDA-CBER-2022-1614-2944610

US3672203
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:23:55
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
User entered '19 Aug 2020 20:31'	System	19 Aug 2020 20:49:04

FDA-CBER-2022-1614-2944611

US3672203
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:23:55
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
User entered '20 Aug 2020 11:59'	System	19 Aug 2020 20:49:04

FDA-CBER-2022-1614-2944612

US3672203
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:23:55
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
Data entry locked.	System	19 Aug 2020 20:49:04
User entered 'Day 2'	System	19 Aug 2020 20:49:04

FDA-CBER-2022-1614-2944613

US3672203
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:23:55
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-20T20:45:59', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '6e420039-a5eb-44a0-b8da-c550c342b970'	System	21 Aug 2020 00:46:10
User entered 'Yes (Y)'	System	21 Aug 2020 00:46:10

FDA-CBER-2022-1614-2944614

US3672203
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:23:55
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-20T20:46:02', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '6e420039-a5eb-44a0-b8da-c550c342b970'	System	21 Aug 2020 00:46:10
User entered '98.9'	System	21 Aug 2020 00:46:10

US3672203
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:23:55
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-20T20:46:05', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '6e420039-a5eb-44a0-b8da-c550c342b970'	System	21 Aug 2020 00:46:10
User entered 'No (N)'	System	21 Aug 2020 00:46:10

US3672203
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:23:55
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-20T20:46:07', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '6e420039-a5eb-44a0-b8da-c550c342b970'	System	21 Aug 2020 00:46:10
User entered '20 Aug 2020 20:46'	System	21 Aug 2020 00:46:10

US3672203
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:23:55
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
User entered '20 Aug 2020 12:00'	System	19 Aug 2020 20:49:04

FDA-CBER-2022-1614-2944618

US3672203
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:23:55
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
User entered '21 Aug 2020 11:59'	System	19 Aug 2020 20:49:04

FDA-CBER-2022-1614-2944619

US3672203
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:23:55
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
Data entry locked.	System	19 Aug 2020 20:49:04
User entered 'Day 3'	System	19 Aug 2020 20:49:04

FDA-CBER-2022-1614-2944620

US3672203
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:23:55
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-21T12:08:22', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '5c9fb192-398a-43bd-8f76-a036b4c63621'	System	21 Aug 2020 16:08:34
User entered 'Yes (Y)'	System	21 Aug 2020 16:08:34

FDA-CBER-2022-1614-2944621

US3672203
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:23:55
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-21T12:08:26', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '5c9fb192-398a-43bd-8f76-a036b4c63621'	System	21 Aug 2020 16:08:34
User entered '98.6'	System	21 Aug 2020 16:08:34

FDA-CBER-2022-1614-2944622

US3672203
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:23:55
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-21T12:08:28', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '5c9fb192-398a-43bd-8f76-a036b4c63621'	System	21 Aug 2020 16:08:34
User entered 'No (N)'	System	21 Aug 2020 16:08:34

US3672203
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:23:55
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-21T12:08:31', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '5c9fb192-398a-43bd-8f76-a036b4c63621'	System	21 Aug 2020 16:08:34
User entered '21 Aug 2020 12:08'	System	21 Aug 2020 16:08:34

FDA-CBER-2022-1614-2944624

US3672203
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:23:55
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 20:49:04

FDA-CBER-2022-1614-2944625

US3672203
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:23:55
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 20:49:04

FDA-CBER-2022-1614-2944626

US3672203
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:23:55
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
Data entry locked.	System	19 Aug 2020 20:49:04
User entered 'Day 4'	System	19 Aug 2020 20:49:04

FDA-CBER-2022-1614-2944627

US3672203
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:23:55
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-22T18:37:53', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: 'c1dce86f-8863-46f7-bcc4-a03b816fd19b'	System	22 Aug 2020 22:38:05
User entered 'Yes (Y)'	System	22 Aug 2020 22:38:05

FDA-CBER-2022-1614-2944628

US3672203
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:23:55
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-22T18:37:57', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: 'c1dce86f-8863-46f7-bcc4-a03b816fd19b'	System	22 Aug 2020 22:38:05
User entered '98.8'	System	22 Aug 2020 22:38:05

FDA-CBER-2022-1614-2944629

US3672203
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:23:55
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-22T18:37:59', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: 'c1dce86f-8863-46f7-bcc4-a03b816fd19b'	System	22 Aug 2020 22:38:05
User entered 'No (N)'	System	22 Aug 2020 22:38:05

FDA-CBER-2022-1614-2944630

US3672203
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:23:55
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-22T18:38:02', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: 'c1dce86f-8863-46f7-bcc4-a03b816fd19b'	System	22 Aug 2020 22:38:05
User entered '22 Aug 2020 18:38'	System	22 Aug 2020 22:38:05

FDA-CBER-2022-1614-2944631

US3672203
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:23:55
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
User entered '22 Aug 2020 12:00'	System	19 Aug 2020 20:49:04

FDA-CBER-2022-1614-2944632

US3672203
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:23:55
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
User entered '23 Aug 2020 11:59'	System	19 Aug 2020 20:49:04

FDA-CBER-2022-1614-2944633

US3672203
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:23:55
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
Data entry locked.	System	19 Aug 2020 20:49:04
User entered 'Day 5'	System	19 Aug 2020 20:49:04

FDA-CBER-2022-1614-2944634

US3672203
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:23:55
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-23T16:58:08', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '2782e567-6c3e-454e-9b97-82196bfcfa9d'	System	23 Aug 2020 20:58:20
User entered 'Yes (Y)'	System	23 Aug 2020 20:58:20

FDA-CBER-2022-1614-2944635

US3672203
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:23:55
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-23T16:58:12', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '2782e567-6c3e-454e-9b97-82196bfcfa9d'	System	23 Aug 2020 20:58:20
User entered '98.6'	System	23 Aug 2020 20:58:20

FDA-CBER-2022-1614-2944636

US3672203
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:23:55
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-23T16:58:14', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '2782e567-6c3e-454e-9b97-82196bfcfa9d'	System	23 Aug 2020 20:58:20
User entered 'No (N)'	System	23 Aug 2020 20:58:20

US3672203
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:23:55
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-23T16:58:17', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '2782e567-6c3e-454e-9b97-82196bfcfa9d'	System	23 Aug 2020 20:58:20
User entered '23 Aug 2020 16:58'	System	23 Aug 2020 20:58:20

FDA-CBER-2022-1614-2944638

US3672203
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:23:55
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
User entered '23 Aug 2020 12:00'	System	19 Aug 2020 20:49:04

FDA-CBER-2022-1614-2944639

US3672203
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:23:55
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
User entered '24 Aug 2020 11:59'	System	19 Aug 2020 20:49:04

FDA-CBER-2022-1614-2944640

US3672203
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:23:55
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
Data entry locked.	System	19 Aug 2020 20:49:04
User entered 'Day 6'	System	19 Aug 2020 20:49:04

FDA-CBER-2022-1614-2944641

US3672203
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:23:55
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-24T21:12:23', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: 'e6f34498-6151-4bd4-a95d-1c3fa7e7c953'	System	25 Aug 2020 01:12:37
User entered 'Yes (Y)'	System	25 Aug 2020 01:12:37

FDA-CBER-2022-1614-2944642

US3672203
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:23:55
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-24T21:12:27', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: 'e6f34498-6151-4bd4-a95d-1c3fa7e7c953'	System	25 Aug 2020 01:12:37
User entered '98.9'	System	25 Aug 2020 01:12:37

FDA-CBER-2022-1614-2944643

US3672203
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:23:55
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-24T21:12:29', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: 'e6f34498-6151-4bd4-a95d-1c3fa7e7c953'	System	25 Aug 2020 01:12:37
User entered 'No (N)'	System	25 Aug 2020 01:12:37

FDA-CBER-2022-1614-2944644

US3672203
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:23:55
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-24T21:12:35', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: 'e6f34498-6151-4bd4-a95d-1c3fa7e7c953'	System	25 Aug 2020 01:12:37
User entered '24 Aug 2020 21:12'	System	25 Aug 2020 01:12:37

FDA-CBER-2022-1614-2944645

US3672203
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:23:55
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
User entered '24 Aug 2020 12:00'	System	19 Aug 2020 20:49:04

FDA-CBER-2022-1614-2944646

US3672203
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:23:55
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
User entered '25 Aug 2020 11:59'	System	19 Aug 2020 20:49:04

FDA-CBER-2022-1614-2944647

US3672203
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:23:55
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
Data entry locked.	System	19 Aug 2020 20:49:04
User entered 'Day 7'	System	19 Aug 2020 20:49:04

FDA-CBER-2022-1614-2944648

US3672203
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:23:55
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-25T18:10:07', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '397eba2b-da41-4494-88cf-acc991517028'	System	25 Aug 2020 22:10:19
User entered 'Yes (Y)'	System	25 Aug 2020 22:10:19

FDA-CBER-2022-1614-2944649

US3672203
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:23:55
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-25T18:10:11', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '397eba2b-da41-4494-88cf-acc991517028'	System	25 Aug 2020 22:10:19
User entered '98.6'	System	25 Aug 2020 22:10:19

FDA-CBER-2022-1614-2944650

US3672203
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:23:55
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-25T18:10:13', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '397eba2b-da41-4494-88cf-acc991517028'	System	25 Aug 2020 22:10:19
User entered 'No (N)'	System	25 Aug 2020 22:10:19

FDA-CBER-2022-1614-2944651

US3672203
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:23:55
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-25T18:10:15', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '397eba2b-da41-4494-88cf-acc991517028'	System	25 Aug 2020 22:10:19
User entered '25 Aug 2020 18:10'	System	25 Aug 2020 22:10:19

FDA-CBER-2022-1614-2944652

US3672203
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:23:55
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
User entered '25 Aug 2020 12:00'	System	19 Aug 2020 20:49:04

FDA-CBER-2022-1614-2944653

US3672203
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:23:55
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
User entered '26 Aug 2020 11:59'	System	19 Aug 2020 20:49:04

FDA-CBER-2022-1614-2944654

US3672203
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:23:55
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
Data entry locked.	System	19 Aug 2020 20:49:04
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Aug 2020 20:49:04

US3672203
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:23:55
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 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-19T17:18:49', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '7847bd2c-5925-4317-bf74-2f834981af72'	System	19 Aug 2020 21:19:07
User entered 'None (1)'	System	19 Aug 2020 21:19:07

FDA-CBER-2022-1614-2944656

US3672203
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:23:55
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-19T17:18:56', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '7847bd2c-5925-4317-bf74-2f834981af72'	System	19 Aug 2020 21:19:07
User entered 'No (N)'	System	19 Aug 2020 21:19:07

US3672203
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:23:55
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-19T17:18:58', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '7847bd2c-5925-4317-bf74-2f834981af72'	System	19 Aug 2020 21:19:07
User entered 'No (N)'	System	19 Aug 2020 21:19:07

FDA-CBER-2022-1614-2944658

US3672203
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:23:55
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 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-19T17:19:01', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '7847bd2c-5925-4317-bf74-2f834981af72'	System	19 Aug 2020 21:19:07
User entered 'None (1)'	System	19 Aug 2020 21:19:07

FDA-CBER-2022-1614-2944659

US3672203
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:23:55
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-19T17:19:04', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '7847bd2c-5925-4317-bf74-2f834981af72'	System	19 Aug 2020 21:19:07
User entered '19 Aug 2020 17:19'	System	19 Aug 2020 21:19:07

FDA-CBER-2022-1614-2944660

US3672203
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:23:55
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
User entered '19 Aug 2020 17:06'	System	19 Aug 2020 20:49:04

FDA-CBER-2022-1614-2944661

US3672203
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:23:55
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
User entered '19 Aug 2020 19:36'	System	19 Aug 2020 20:49:04

FDA-CBER-2022-1614-2944662

US3672203
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:23:55
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
Data entry locked.	System	19 Aug 2020 20:49:04
User entered 'Day 1, after vaccination (at home)'	System	19 Aug 2020 20:49:04

US3672203
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:23:55
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 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-19T20:32:51', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: 'b38fdcc5-02ae-4bd8-90fb-6d78a0c5f508'	System	20 Aug 2020 00:33:31
User entered 'None (1)'	System	20 Aug 2020 00:33:31

US3672203
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:23:55
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-19T20:33:01', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: 'b38fdcc5-02ae-4bd8-90fb-6d78a0c5f508'	System	20 Aug 2020 00:33:31
User entered 'No (N)'	System	20 Aug 2020 00:33:31

US3672203
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:23:55
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-19T20:33:10', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: 'b38fdcc5-02ae-4bd8-90fb-6d78a0c5f508'	System	20 Aug 2020 00:33:31
User entered 'No (N)'	System	20 Aug 2020 00:33:31

US3672203
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:23:55
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 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-19T20:33:24', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: 'b38fdcc5-02ae-4bd8-90fb-6d78a0c5f508'	System	20 Aug 2020 00:33:31
User entered 'None (1)'	System	20 Aug 2020 00:33:31

FDA-CBER-2022-1614-2944667

US3672203
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:23:55
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-19T20:33:26', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: 'b38fdcc5-02ae-4bd8-90fb-6d78a0c5f508'	System	20 Aug 2020 00:33:31
User entered '19 Aug 2020 20:33'	System	20 Aug 2020 00:33:31

FDA-CBER-2022-1614-2944668

US3672203
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:23:55
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
User entered '19 Aug 2020 20:31'	System	19 Aug 2020 20:49:04

FDA-CBER-2022-1614-2944669

US3672203
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:23:55
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
User entered '20 Aug 2020 11:59'	System	19 Aug 2020 20:49:04

FDA-CBER-2022-1614-2944670

US3672203
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:23:55
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
Data entry locked.	System	19 Aug 2020 20:49:04
User entered 'Day 2'	System	19 Aug 2020 20:49:04

FDA-CBER-2022-1614-2944671

US3672203
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:23:55
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 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-20T20:46:13', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '2154e7e9-5b88-4907-bc87-912643ca521a'	System	21 Aug 2020 00:46:28
User entered 'None (1)'	System	21 Aug 2020 00:46:28

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US3672203
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:23:55
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-20T20:46:17', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '2154e7e9-5b88-4907-bc87-912643ca521a'	System	21 Aug 2020 00:46:28
User entered 'No (N)'	System	21 Aug 2020 00:46:28

US3672203
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:23:55
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-20T20:46:21', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '2154e7e9-5b88-4907-bc87-912643ca521a'	System	21 Aug 2020 00:46:28
User entered 'No (N)'	System	21 Aug 2020 00:46:28

US3672203
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:23:55
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 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-20T20:46:23', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '2154e7e9-5b88-4907-bc87-912643ca521a'	System	21 Aug 2020 00:46:28
User entered 'None (1)'	System	21 Aug 2020 00:46:28

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US3672203
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:23:55
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-20T20:46:26', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '2154e7e9-5b88-4907-bc87-912643ca521a'	System	21 Aug 2020 00:46:28
User entered '20 Aug 2020 20:46'	System	21 Aug 2020 00:46:28

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US3672203
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:23:55
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
User entered '20 Aug 2020 12:00'	System	19 Aug 2020 20:49:04

FDA-CBER-2022-1614-2944677

US3672203
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:23:55
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
User entered '21 Aug 2020 11:59'	System	19 Aug 2020 20:49:04

FDA-CBER-2022-1614-2944678

US3672203
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:23:55
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
Data entry locked.	System	19 Aug 2020 20:49:04
User entered 'Day 3'	System	19 Aug 2020 20:49:04

FDA-CBER-2022-1614-2944679

US3672203
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:23:55
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 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-21T12:07:53', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '9c81b14a-d42e-4136-bb1d-6c82488a45b2'	System	21 Aug 2020 16:08:21
User entered 'None (1)'	System	21 Aug 2020 16:08:21

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US3672203
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:23:55
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-21T12:07:58', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '9c81b14a-d42e-4136-bb1d-6c82488a45b2'	System	21 Aug 2020 16:08:21
User entered 'No (N)'	System	21 Aug 2020 16:08:21

US3672203
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:23:55
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-21T12:08:01', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '9c81b14a-d42e-4136-bb1d-6c82488a45b2'	System	21 Aug 2020 16:08:21
User entered 'No (N)'	System	21 Aug 2020 16:08:21

US3672203
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:23:55
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 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-21T12:08:09', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '9c81b14a-d42e-4136-bb1d-6c82488a45b2'	System	21 Aug 2020 16:08:21
User entered 'None (1)'	System	21 Aug 2020 16:08:21

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US3672203
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:23:55
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-21T12:08:17', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '9c81b14a-d42e-4136-bb1d-6c82488a45b2'	System	21 Aug 2020 16:08:21
User entered '21 Aug 2020 12:08'	System	21 Aug 2020 16:08:21

US3672203
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:23:55
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 20:49:04

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US3672203
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:23:55
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 20:49:04

FDA-CBER-2022-1614-2944686

US3672203
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:23:55
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
Data entry locked.	System	19 Aug 2020 20:49:04
User entered 'Day 4'	System	19 Aug 2020 20:49:04

FDA-CBER-2022-1614-2944687

US3672203
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:23:55
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 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-22T18:38:05', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: 'dbde40e5-480e-462e-9f2e-2adb76657c9b'	System	22 Aug 2020 22:38:17
User entered 'None (1)'	System	22 Aug 2020 22:38:17

US3672203
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:23:55
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-22T18:38:08', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: 'dbde40e5-480e-462e-9f2e-2adb76657c9b'	System	22 Aug 2020 22:38:17
User entered 'No (N)'	System	22 Aug 2020 22:38:17

US3672203
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:23:55
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-22T18:38:10', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: 'dbde40e5-480e-462e-9f2e-2adb76657c9b'	System	22 Aug 2020 22:38:17
User entered 'No (N)'	System	22 Aug 2020 22:38:17

US3672203
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:23:55
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 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-22T18:38:12', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: 'dbde40e5-480e-462e-9f2e-2adb76657c9b'	System	22 Aug 2020 22:38:17
User entered 'None (1)'	System	22 Aug 2020 22:38:17

US3672203
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:23:55
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-22T18:38:14', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: 'dbde40e5-480e-462e-9f2e-2adb76657c9b'	System	22 Aug 2020 22:38:17
User entered '22 Aug 2020 18:38'	System	22 Aug 2020 22:38:17

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US3672203
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:23:55
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
User entered '22 Aug 2020 12:00'	System	19 Aug 2020 20:49:04

FDA-CBER-2022-1614-2944693

US3672203
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:23:55
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
User entered '23 Aug 2020 11:59'	System	19 Aug 2020 20:49:04

FDA-CBER-2022-1614-2944694

US3672203
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:23:55
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
Data entry locked.	System	19 Aug 2020 20:49:04
User entered 'Day 5'	System	19 Aug 2020 20:49:04

FDA-CBER-2022-1614-2944695

US3672203
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:23:55
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 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-23T16:58:20', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '1a57455e-8c33-42e6-8a1c-f7b0f1ecaf87'	System	23 Aug 2020 20:58:30
User entered 'None (1)'	System	23 Aug 2020 20:58:30

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US3672203
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:23:55
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-23T16:58:22', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '1a57455e-8c33-42e6-8a1c-f7b0f1ecaf87'	System	23 Aug 2020 20:58:30
User entered 'No (N)'	System	23 Aug 2020 20:58:30

US3672203
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:23:55
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-23T16:58:24', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '1a57455e-8c33-42e6-8a1c-f7b0f1ecaf87'	System	23 Aug 2020 20:58:30
User entered 'No (N)'	System	23 Aug 2020 20:58:30

US3672203
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:23:55
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 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-23T16:58:26', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '1a57455e-8c33-42e6-8a1c-f7b0f1ecaf87'	System	23 Aug 2020 20:58:30
User entered 'None (1)'	System	23 Aug 2020 20:58:30

FDA-CBER-2022-1614-2944699

US3672203
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:23:55
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-23T16:58:28', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '1a57455e-8c33-42e6-8a1c-f7b0f1ecaf87'	System	23 Aug 2020 20:58:30
User entered '23 Aug 2020 16:58'	System	23 Aug 2020 20:58:30

US3672203
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:23:55
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
User entered '23 Aug 2020 12:00'	System	19 Aug 2020 20:49:04

FDA-CBER-2022-1614-2944701

US3672203
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:23:55
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
User entered '24 Aug 2020 11:59'	System	19 Aug 2020 20:49:04

FDA-CBER-2022-1614-2944702

US3672203
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:23:55
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
Data entry locked.	System	19 Aug 2020 20:49:04
User entered 'Day 6'	System	19 Aug 2020 20:49:04

US3672203
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:23:55
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 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-24T21:12:59', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '2e994277-ff2d-424f-9b13-ad286e10b668'	System	25 Aug 2020 01:13:17
User entered 'None (1)'	System	25 Aug 2020 01:13:17

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US3672203
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:23:55
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-24T21:13:08', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '2e994277-ff2d-424f-9b13-ad286e10b668'	System	25 Aug 2020 01:13:17
User entered 'No (N)'	System	25 Aug 2020 01:13:17

US3672203
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:23:55
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-24T21:13:10', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '2e994277-ff2d-424f-9b13-ad286e10b668'	System	25 Aug 2020 01:13:17
User entered 'No (N)'	System	25 Aug 2020 01:13:17

FDA-CBER-2022-1614-2944706

US3672203
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:23:55
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 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-24T21:13:12', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '2e994277-ff2d-424f-9b13-ad286e10b668'	System	25 Aug 2020 01:13:17
User entered 'None (1)'	System	25 Aug 2020 01:13:17

US3672203
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:23:55
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-24T21:13:14', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '2e994277-ff2d-424f-9b13-ad286e10b668'	System	25 Aug 2020 01:13:17
User entered '24 Aug 2020 21:13'	System	25 Aug 2020 01:13:17

FDA-CBER-2022-1614-2944708

US3672203
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:23:55
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
User entered '24 Aug 2020 12:00'	System	19 Aug 2020 20:49:04

FDA-CBER-2022-1614-2944709

US3672203
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:23:55
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
User entered '25 Aug 2020 11:59'	System	19 Aug 2020 20:49:04

FDA-CBER-2022-1614-2944710

US3672203
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:23:55
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
Data entry locked.	System	19 Aug 2020 20:49:04
User entered 'Day 7'	System	19 Aug 2020 20:49:04

FDA-CBER-2022-1614-2944711

US3672203
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:23:55
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 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-25T18:10:18', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '1b7c1188-9ee3-4a1b-88ca-19458840a4d1'	System	25 Aug 2020 22:10:27
User entered 'None (1)'	System	25 Aug 2020 22:10:27

FDA-CBER-2022-1614-2944712

US3672203
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:23:55
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-25T18:10:20', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '1b7c1188-9ee3-4a1b-88ca-19458840a4d1'	System	25 Aug 2020 22:10:27
User entered 'No (N)'	System	25 Aug 2020 22:10:27

US3672203
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:23:55
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-25T18:10:22', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '1b7c1188-9ee3-4a1b-88ca-19458840a4d1'	System	25 Aug 2020 22:10:27
User entered 'No (N)'	System	25 Aug 2020 22:10:27

US3672203
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:23:55
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 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-25T18:10:23', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '1b7c1188-9ee3-4a1b-88ca-19458840a4d1'	System	25 Aug 2020 22:10:27
User entered 'None (1)'	System	25 Aug 2020 22:10:27

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US3672203
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:23:55
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-25T18:10:25', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '1b7c1188-9ee3-4a1b-88ca-19458840a4d1'	System	25 Aug 2020 22:10:27
User entered '25 Aug 2020 18:10'	System	25 Aug 2020 22:10:27

US3672203
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:23:55
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
User entered '25 Aug 2020 12:00'	System	19 Aug 2020 20:49:04

FDA-CBER-2022-1614-2944717

US3672203
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:23:55
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
User entered '26 Aug 2020 11:59'	System	19 Aug 2020 20:49:04

FDA-CBER-2022-1614-2944718

US3672203
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:23:55
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
Data entry locked.	System	19 Aug 2020 20:49:04
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Aug 2020 20:49:04

US3672203
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:23:55
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-19T17:19:23', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '34886812-b625-49d8-b6d2-8e1eeb3995d8'	System	19 Aug 2020 21:19:49
User entered 'None (0)'	System	19 Aug 2020 21:19:49

US3672203
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:23:55
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-19T17:19:24', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '34886812-b625-49d8-b6d2-8e1eeb3995d8'	System	19 Aug 2020 21:19:49
User entered 'None (0)'	System	19 Aug 2020 21:19:49

US3672203
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:23:55
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-19T17:19:26', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '34886812-b625-49d8-b6d2-8e1eeb3995d8'	System	19 Aug 2020 21:19:49
User entered 'None (0)'	System	19 Aug 2020 21:19:49

FDA-CBER-2022-1614-2944722

US3672203
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:23:55
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-19T17:19:27', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '34886812-b625-49d8-b6d2-8e1eeb3995d8'	System	19 Aug 2020 21:19:49
User entered 'None (0)'	System	19 Aug 2020 21:19:49

FDA-CBER-2022-1614-2944723

US3672203
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:23:55
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-19T17:19:31', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '34886812-b625-49d8-b6d2-8e1eeb3995d8'	System	19 Aug 2020 21:19:49
User entered 'None (0)'	System	19 Aug 2020 21:19:49

FDA-CBER-2022-1614-2944724

US3672203
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:23:55
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-19T17:19:37', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '34886812-b625-49d8-b6d2-8e1eeb3995d8'	System	19 Aug 2020 21:19:49
User entered 'None (0)'	System	19 Aug 2020 21:19:49

US3672203
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:23:55
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 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-19T17:19:42', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '34886812-b625-49d8-b6d2-8e1eeb3995d8'	System	19 Aug 2020 21:19:49
User entered 'No (N)'	System	19 Aug 2020 21:19:49

FDA-CBER-2022-1614-2944726

US3672203
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:23:55
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-19T17:19:44', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '34886812-b625-49d8-b6d2-8e1eeb3995d8'	System	19 Aug 2020 21:19:49
User entered '19 Aug 2020 17:19'	System	19 Aug 2020 21:19:49

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US3672203
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:23:55
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
User entered '19 Aug 2020 17:06'	System	19 Aug 2020 20:49:04

FDA-CBER-2022-1614-2944728

US3672203
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:23:55
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
User entered '19 Aug 2020 19:36'	System	19 Aug 2020 20:49:04

FDA-CBER-2022-1614-2944729

US3672203
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:23:55
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
Data entry locked.	System	19 Aug 2020 20:49:04
User entered 'Day 1, after vaccination (at home)'	System	19 Aug 2020 20:49:04

US3672203
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:23:55
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-19T20:33:33', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '6f2a3a6d-f57e-4cac-b30a-6701f6829399'	System	20 Aug 2020 00:34:28
User entered 'None (0)'	System	20 Aug 2020 00:34:28

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US3672203
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:23:55
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-19T20:33:45', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '6f2a3a6d-f57e-4cac-b30a-6701f6829399'	System	20 Aug 2020 00:34:28
User entered 'None (0)'	System	20 Aug 2020 00:34:28

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US3672203
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:23:55
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-19T20:33:48', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '6f2a3a6d-f57e-4cac-b30a-6701f6829399'	System	20 Aug 2020 00:34:28
User entered 'None (0)'	System	20 Aug 2020 00:34:28

FDA-CBER-2022-1614-2944733

US3672203
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:23:55
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-19T20:33:53', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '6f2a3a6d-f57e-4cac-b30a-6701f6829399'	System	20 Aug 2020 00:34:28
User entered 'None (0)'	System	20 Aug 2020 00:34:28

FDA-CBER-2022-1614-2944734

US3672203
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:23:55
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-19T20:33:56', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '6f2a3a6d-f57e-4cac-b30a-6701f6829399'	System	20 Aug 2020 00:34:28
User entered 'None (0)'	System	20 Aug 2020 00:34:28

FDA-CBER-2022-1614-2944735

US3672203
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:23:55
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-19T20:34:00', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '6f2a3a6d-f57e-4cac-b30a-6701f6829399'	System	20 Aug 2020 00:34:28
User entered 'None (0)'	System	20 Aug 2020 00:34:28

FDA-CBER-2022-1614-2944736

US3672203
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:23:55
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 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-19T20:34:19', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '6f2a3a6d-f57e-4cac-b30a-6701f6829399'	System	20 Aug 2020 00:34:28
User entered 'No (N)'	System	20 Aug 2020 00:34:28

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US3672203
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:23:55
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-19T20:34:24', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '6f2a3a6d-f57e-4cac-b30a-6701f6829399'	System	20 Aug 2020 00:34:28
User entered '19 Aug 2020 20:34'	System	20 Aug 2020 00:34:28

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US3672203
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:23:55
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
User entered '19 Aug 2020 20:31'	System	19 Aug 2020 20:49:04

FDA-CBER-2022-1614-2944739

US3672203
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:23:55
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
User entered '20 Aug 2020 11:59'	System	19 Aug 2020 20:49:04

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US3672203
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:23:55
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
Data entry locked.	System	19 Aug 2020 20:49:04
User entered 'Day 2'	System	19 Aug 2020 20:49:04

US3672203
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:23:55
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-20T20:46:32', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '0d2d7062-fc29-499d-a2c3-c04334689165'	System	21 Aug 2020 00:46:55
User entered 'None (0)'	System	21 Aug 2020 00:46:55

FDA-CBER-2022-1614-2944742

US3672203
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:23:55
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-20T20:46:35', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '0d2d7062-fc29-499d-a2c3-c04334689165'	System	21 Aug 2020 00:46:55
User entered 'None (0)'	System	21 Aug 2020 00:46:55

FDA-CBER-2022-1614-2944743

US3672203
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:23:55
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-20T20:46:36', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '0d2d7062-fc29-499d-a2c3-c04334689165'	System	21 Aug 2020 00:46:55
User entered 'None (0)'	System	21 Aug 2020 00:46:55

FDA-CBER-2022-1614-2944744

US3672203
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:23:55
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-20T20:46:39', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '0d2d7062-fc29-499d-a2c3-c04334689165'	System	21 Aug 2020 00:46:55
User entered 'None (0)'	System	21 Aug 2020 00:46:55

FDA-CBER-2022-1614-2944745

US3672203
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:23:55
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-20T20:46:41', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '0d2d7062-fc29-499d-a2c3-c04334689165'	System	21 Aug 2020 00:46:55
User entered 'None (0)'	System	21 Aug 2020 00:46:55

FDA-CBER-2022-1614-2944746

US3672203
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:23:55
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-20T20:46:43', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '0d2d7062-fc29-499d-a2c3-c04334689165'	System	21 Aug 2020 00:46:55
User entered 'None (0)'	System	21 Aug 2020 00:46:55

FDA-CBER-2022-1614-2944747

US3672203
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:23:55
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 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-20T20:46:48', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '0d2d7062-fc29-499d-a2c3-c04334689165'	System	21 Aug 2020 00:46:55
User entered 'No (N)'	System	21 Aug 2020 00:46:55

FDA-CBER-2022-1614-2944748

US3672203
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:23:55
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-20T20:46:51', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '0d2d7062-fc29-499d-a2c3-c04334689165'	System	21 Aug 2020 00:46:55
User entered '20 Aug 2020 20:46'	System	21 Aug 2020 00:46:55

FDA-CBER-2022-1614-2944749

US3672203
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:23:55
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
User entered '20 Aug 2020 12:00'	System	19 Aug 2020 20:49:04

US3672203
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:23:55
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
User entered '21 Aug 2020 11:59'	System	19 Aug 2020 20:49:04

FDA-CBER-2022-1614-2944751

US3672203
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:23:55
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
Data entry locked.	System	19 Aug 2020 20:49:04
User entered 'Day 3'	System	19 Aug 2020 20:49:04

US3672203
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:23:55
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-21T12:08:34', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '49dcf4e0-c2e4-45ee-9eba-4860feb6ba42'	System	21 Aug 2020 16:08:57
User entered 'None (0)'	System	21 Aug 2020 16:08:57

US3672203
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:23:55
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-21T12:08:36', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '49dcf4e0-c2e4-45ee-9eba-4860feb6ba42'	System	21 Aug 2020 16:08:57
User entered 'None (0)'	System	21 Aug 2020 16:08:57

FDA-CBER-2022-1614-2944754

US3672203
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:23:55
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-21T12:08:37', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '49dcf4e0-c2e4-45ee-9eba-4860feb6ba42'	System	21 Aug 2020 16:08:57
User entered 'None (0)'	System	21 Aug 2020 16:08:57

US3672203
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:23:55
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-21T12:08:39', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '49dcf4e0-c2e4-45ee-9eba-4860feb6ba42'	System	21 Aug 2020 16:08:57
User entered 'None (0)'	System	21 Aug 2020 16:08:57

FDA-CBER-2022-1614-2944756

US3672203
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:23:55
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-21T12:08:40', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '49dcf4e0-c2e4-45ee-9eba-4860feb6ba42'	System	21 Aug 2020 16:08:57
User entered 'None (0)'	System	21 Aug 2020 16:08:57

US3672203
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:23:55
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-21T12:08:44', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '49dcf4e0-c2e4-45ee-9eba-4860feb6ba42'	System	21 Aug 2020 16:08:57
User entered 'None (0)'	System	21 Aug 2020 16:08:57

US3672203
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:23:55
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 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-21T12:08:50', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '49dcf4e0-c2e4-45ee-9eba-4860feb6ba42'	System	21 Aug 2020 16:08:57
User entered 'Yes (Y)'	System	21 Aug 2020 16:08:57

FDA-CBER-2022-1614-2944759

US3672203
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:23:55
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-21T12:08:54', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '49dcf4e0-c2e4-45ee-9eba-4860feb6ba42'	System	21 Aug 2020 16:08:57
User entered '21 Aug 2020 12:08'	System	21 Aug 2020 16:08:57

US3672203
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:23:55
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 20:49:04

FDA-CBER-2022-1614-2944761

US3672203
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:23:55
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 20:49:04

FDA-CBER-2022-1614-2944762

US3672203
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:23:55
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
Data entry locked.	System	19 Aug 2020 20:49:04
User entered 'Day 4'	System	19 Aug 2020 20:49:04

US3672203
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:23:55
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-22T18:38:18', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: 'cb08b04c-51dd-48b5-90ac-e158027ca031'	System	22 Aug 2020 22:38:43
User entered 'None (0)'	System	22 Aug 2020 22:38:43

US3672203
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:23:55
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-22T18:38:21', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: 'cb08b04c-51dd-48b5-90ac-e158027ca031'	System	22 Aug 2020 22:38:43
User entered 'None (0)'	System	22 Aug 2020 22:38:43

US3672203
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:23:55
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-22T18:38:23', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: 'cb08b04c-51dd-48b5-90ac-e158027ca031'	System	22 Aug 2020 22:38:43
User entered 'None (0)'	System	22 Aug 2020 22:38:43

US3672203
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:23:55
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-22T18:38:26', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: 'cb08b04c-51dd-48b5-90ac-e158027ca031'	System	22 Aug 2020 22:38:43
User entered 'None (0)'	System	22 Aug 2020 22:38:43

US3672203
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:23:55
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-22T18:38:29', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: 'cb08b04c-51dd-48b5-90ac-e158027ca031'	System	22 Aug 2020 22:38:43
User entered 'None (0)'	System	22 Aug 2020 22:38:43

FDA-CBER-2022-1614-2944768

US3672203
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:23:55
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-22T18:38:31', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: 'cb08b04c-51dd-48b5-90ac-e158027ca031'	System	22 Aug 2020 22:38:43
User entered 'None (0)'	System	22 Aug 2020 22:38:43

FDA-CBER-2022-1614-2944769

US3672203
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:23:55
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 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-22T18:38:36', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: 'cb08b04c-51dd-48b5-90ac-e158027ca031'	System	22 Aug 2020 22:38:43
User entered 'No (N)'	System	22 Aug 2020 22:38:43

US3672203
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:23:55
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-22T18:38:39', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: 'cb08b04c-51dd-48b5-90ac-e158027ca031'	System	22 Aug 2020 22:38:43
User entered '22 Aug 2020 18:38'	System	22 Aug 2020 22:38:43

FDA-CBER-2022-1614-2944771

US3672203
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:23:55
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
User entered '22 Aug 2020 12:00'	System	19 Aug 2020 20:49:04

FDA-CBER-2022-1614-2944772

US3672203
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:23:55
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
User entered '23 Aug 2020 11:59'	System	19 Aug 2020 20:49:04

FDA-CBER-2022-1614-2944773

US3672203
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:23:55
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
Data entry locked.	System	19 Aug 2020 20:49:04
User entered 'Day 5'	System	19 Aug 2020 20:49:04

FDA-CBER-2022-1614-2944774

US3672203
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:23:55
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-23T16:58:41', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: 'aeb0cb85-d2ac-4cec-84c1-93a56319357e'	System	23 Aug 2020 20:58:57
User entered 'No interference with activity (1)'	System	23 Aug 2020 20:58:57

FDA-CBER-2022-1614-2944775

US3672203
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:23:55
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-23T16:58:43', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: 'aeb0cb85-d2ac-4cec-84c1-93a56319357e'	System	23 Aug 2020 20:58:57
User entered 'None (0)'	System	23 Aug 2020 20:58:57

FDA-CBER-2022-1614-2944776

US3672203
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:23:55
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-23T16:58:44', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: 'aeb0cb85-d2ac-4cec-84c1-93a56319357e'	System	23 Aug 2020 20:58:57
User entered 'None (0)'	System	23 Aug 2020 20:58:57

FDA-CBER-2022-1614-2944777

US3672203
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:23:55
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-23T16:58:46', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: 'aeb0cb85-d2ac-4cec-84c1-93a56319357e'	System	23 Aug 2020 20:58:57
User entered 'None (0)'	System	23 Aug 2020 20:58:57

US3672203
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:23:55
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-23T16:58:48', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: 'aeb0cb85-d2ac-4cec-84c1-93a56319357e'	System	23 Aug 2020 20:58:57
User entered 'None (0)'	System	23 Aug 2020 20:58:57

FDA-CBER-2022-1614-2944779

US3672203
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:23:55
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-23T16:58:49', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: 'aeb0cb85-d2ac-4cec-84c1-93a56319357e'	System	23 Aug 2020 20:58:57
User entered 'None (0)'	System	23 Aug 2020 20:58:57

US3672203
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:23:55
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 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-23T16:58:52', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: 'aeb0cb85-d2ac-4cec-84c1-93a56319357e'	System	23 Aug 2020 20:58:57
User entered 'No (N)'	System	23 Aug 2020 20:58:57

FDA-CBER-2022-1614-2944781

US3672203
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:23:55
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-23T16:58:54', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: 'aeb0cb85-d2ac-4cec-84c1-93a56319357e'	System	23 Aug 2020 20:58:57
User entered '23 Aug 2020 16:58'	System	23 Aug 2020 20:58:57

FDA-CBER-2022-1614-2944782

US3672203
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:23:55
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
User entered '23 Aug 2020 12:00'	System	19 Aug 2020 20:49:04

FDA-CBER-2022-1614-2944783

US3672203
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:23:55
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
User entered '24 Aug 2020 11:59'	System	19 Aug 2020 20:49:04

FDA-CBER-2022-1614-2944784

US3672203
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:23:55
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
Data entry locked.	System	19 Aug 2020 20:49:04
User entered 'Day 6'	System	19 Aug 2020 20:49:04

FDA-CBER-2022-1614-2944785

US3672203
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:23:55
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-24T21:13:18', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '2e708079-f27b-4343-8e56-dfcce4c98cd7'	System	25 Aug 2020 01:13:35
User entered 'None (0)'	System	25 Aug 2020 01:13:35

FDA-CBER-2022-1614-2944786

US3672203
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:23:55
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-24T21:13:21', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '2e708079-f27b-4343-8e56-dfcce4c98cd7'	System	25 Aug 2020 01:13:35
User entered 'None (0)'	System	25 Aug 2020 01:13:35

FDA-CBER-2022-1614-2944787

US3672203
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:23:55
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-24T21:13:22', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '2e708079-f27b-4343-8e56-dfcce4c98cd7'	System	25 Aug 2020 01:13:35
User entered 'None (0)'	System	25 Aug 2020 01:13:35

FDA-CBER-2022-1614-2944788

US3672203
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:23:55
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-24T21:13:24', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '2e708079-f27b-4343-8e56-dfcce4c98cd7'	System	25 Aug 2020 01:13:35
User entered 'None (0)'	System	25 Aug 2020 01:13:35

FDA-CBER-2022-1614-2944789

US3672203
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:23:55
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-24T21:13:27', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '2e708079-f27b-4343-8e56-dfcce4c98cd7'	System	25 Aug 2020 01:13:35
User entered 'None (0)'	System	25 Aug 2020 01:13:35

US3672203
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:23:55
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-24T21:13:28', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '2e708079-f27b-4343-8e56-dfcce4c98cd7'	System	25 Aug 2020 01:13:35
User entered 'None (0)'	System	25 Aug 2020 01:13:35

FDA-CBER-2022-1614-2944791

US3672203
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:23:55
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 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-24T21:13:31', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '2e708079-f27b-4343-8e56-dfcce4c98cd7'	System	25 Aug 2020 01:13:35
User entered 'No (N)'	System	25 Aug 2020 01:13:35

FDA-CBER-2022-1614-2944792

US3672203
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:23:55
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-24T21:13:32', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '2e708079-f27b-4343-8e56-dfcce4c98cd7'	System	25 Aug 2020 01:13:35
User entered '24 Aug 2020 21:13'	System	25 Aug 2020 01:13:35

FDA-CBER-2022-1614-2944793

US3672203
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:23:55
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
User entered '24 Aug 2020 12:00'	System	19 Aug 2020 20:49:04

FDA-CBER-2022-1614-2944794

US3672203
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:23:55
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
User entered '25 Aug 2020 11:59'	System	19 Aug 2020 20:49:04

FDA-CBER-2022-1614-2944795

US3672203
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:23:55
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
Data entry locked.	System	19 Aug 2020 20:49:04
User entered 'Day 7'	System	19 Aug 2020 20:49:04

FDA-CBER-2022-1614-2944796

US3672203
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:23:55
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-25T18:10:27', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '7af0f18e-28c9-46c8-beee-3108dda177c9'	System	25 Aug 2020 22:10:46
User entered 'None (0)'	System	25 Aug 2020 22:10:46

FDA-CBER-2022-1614-2944797

US3672203
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:23:55
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-25T18:10:29', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '7af0f18e-28c9-46c8-beee-3108dda177c9'	System	25 Aug 2020 22:10:46
User entered 'None (0)'	System	25 Aug 2020 22:10:46

FDA-CBER-2022-1614-2944798

US3672203
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:23:55
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-25T18:10:30', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '7af0f18e-28c9-46c8-beee-3108dda177c9'	System	25 Aug 2020 22:10:46
User entered 'None (0)'	System	25 Aug 2020 22:10:46

FDA-CBER-2022-1614-2944799

US3672203
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:23:55
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-25T18:10:32', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '7af0f18e-28c9-46c8-beee-3108dda177c9'	System	25 Aug 2020 22:10:46
User entered 'None (0)'	System	25 Aug 2020 22:10:46

US3672203
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:23:55
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-25T18:10:33', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '7af0f18e-28c9-46c8-beee-3108dda177c9'	System	25 Aug 2020 22:10:46
User entered 'None (0)'	System	25 Aug 2020 22:10:46

FDA-CBER-2022-1614-2944801

US3672203
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:23:55
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-25T18:10:34', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '7af0f18e-28c9-46c8-beee-3108dda177c9'	System	25 Aug 2020 22:10:46
User entered 'None (0)'	System	25 Aug 2020 22:10:46

US3672203
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:23:55
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 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-25T18:10:40', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '7af0f18e-28c9-46c8-beee-3108dda177c9'	System	25 Aug 2020 22:10:46
User entered 'No (N)'	System	25 Aug 2020 22:10:46

US3672203
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:23:55
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-08-25T18:10:42', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '7af0f18e-28c9-46c8-beee-3108dda177c9'	System	25 Aug 2020 22:10:46
User entered '25 Aug 2020 18:10'	System	25 Aug 2020 22:10:46

FDA-CBER-2022-1614-2944804

US3672203
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:23:55
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
User entered '25 Aug 2020 12:00'	System	19 Aug 2020 20:49:04

FDA-CBER-2022-1614-2944805

US3672203
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:23:55
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
User entered '26 Aug 2020 11:59'	System	19 Aug 2020 20:49:04

FDA-CBER-2022-1614-2944806

US3672203
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:23:55
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:46:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Aug 2020 18:10:49

FDA-CBER-2022-1614-2944807

US3672203
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:23:55
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:46:04
User entered '26 Aug 2020'	(b) (4), (b) (6)	26 Aug 2020 18:10:49

FDA-CBER-2022-1614-2944808

US3672203
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:23:55
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:46:04
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	26 Aug 2020 18:10:49

US3672203
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:23:55
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:46:04
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 18:10:49

US3672203
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:23:55
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:46:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Aug 2020 18:10:52

FDA-CBER-2022-1614-2944811

US3672203
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:23:55
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User entered '1'	System	26 Aug 2020 18:10:52

US3672203
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:23:55
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 20:02:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Sep 2020 19:45:13

US3672203
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:23:55
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
User closed query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	24 Sep 2020 13:23:46
Query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'confirm' (Site from System).	(b) (4), (b) (6)	23 Sep 2020 19:07:49
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 20:02:44
User opened query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	09 Sep 2020 19:45:13
User entered '08 Sep 2020'	(b) (4), (b) (6)	09 Sep 2020 19:45:13

US3672203
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:23:55
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 20:02:44
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	09 Sep 2020 19:45:13

US3672203
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:23:55
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 20:02:44
User entered empty.	(b) (4), (b) (6)	09 Sep 2020 19:45:13

FDA-CBER-2022-1614-2944816

US3672203
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:23:55
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:07:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Sep 2020 19:45:18

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US3672203
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:23:55
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User entered '1'	System	09 Sep 2020 19:45:18

US3672203
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:23:55
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 17:01:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 14:42:58

US3672203
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:23:55
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 17:01:59
User entered '11 Sep 2020'	(b) (4), (b) (6)	23 Sep 2020 14:42:58

US3672203
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:23:55
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 17:01:59
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	23 Sep 2020 14:42:58

US3672203
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:23:55
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 17:01:59
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 14:42:58

US3672203
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:23:55
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
User closed query 'Please complete page one of the Day 22 Safety Call as expected.' (Site from CRA).	(b) (4), (b) (6)	23 Sep 2020 17:02:07
Query 'Please complete page one of the Day 22 Safety Call as expected.' answered with 'completed.' (Site from CRA).	(b) (4), (b) (6)	23 Sep 2020 14:43:06
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 20:00:30
User opened query 'Please complete page one of the Day 22 Safety Call as expected.' (Site from CRA).	(b) (4), (b) (6)	22 Sep 2020 20:00:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Sep 2020 17:41:07

US3672203
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:23:55
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User entered '1'	System	18 Sep 2020 17:41:07

US3672203
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:23:55
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:11
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:01:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 19:40:27

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US3672203
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:23:55
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:11
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:01:07
User entered '18 Sep 2020'	(b) (4), (b) (6)	21 Sep 2020 19:40:27

US3672203
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:23:55
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 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:11
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:01:07
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	21 Sep 2020 19:40:27

US3672203
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:23:55
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User entered 'VISIT2'	System	21 Sep 2020 19:40:27

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US3672203
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:23:55
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	21 Sep 2020 19:40:33

US3672203
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:23:55
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:11
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:02:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 19:40:33

US3672203
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:23:55
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:03:11
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:02:00
User closed query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 19:41:17
User entered '18 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 19:41:17
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 19:40:33
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 19:40:33

US3672203
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:23:55
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:03:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:02:00
User closed query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 19:41:17
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	21 Sep 2020 19:41:17
User entered '12:46' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 19:41:17
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 19:40:33
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 19:40:33

US3672203
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:23:55
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User entered '18 Sep 2020 12:46'	System	21 Sep 2020 19:41:17
User entered empty.	System	21 Sep 2020 19:40:33

US3672203
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:23:55
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:03:11
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:02:00
User closed query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 19:41:17
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	21 Sep 2020 19:41:17
User entered '98.6' F reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 19:41:17
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 19:40:33
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 19:40:33

US3672203
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:23:55
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:03:11
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:02:00
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 19:41:17
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 19:40:33

US3672203
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:23:55
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:11
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:02:00
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 19:40:33

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US3672203
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:23:55
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:03:11
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:02:00
User closed query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 19:41:17
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	21 Sep 2020 19:41:17
User entered '74' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 19:41:17
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 19:40:33
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 19:40:33

US3672203
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:23:55
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User entered 'bpm'	System	21 Sep 2020 19:41:17
User entered empty.	System	21 Sep 2020 19:40:33

US3672203
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:23:55
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:03:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:02:00
User closed query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 19:41:17
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	21 Sep 2020 19:41:17
User entered '15' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 19:41:17
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 19:40:33
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 19:40:33

US3672203
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:23:55
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User entered 'breaths/min'	System	21 Sep 2020 19:41:17
User entered empty.	System	21 Sep 2020 19:40:33

US3672203
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:23:55
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:03:11
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:02:00
User closed query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 19:41:17
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	21 Sep 2020 19:41:17
User entered '141' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 19:41:17
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 19:40:33
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 19:40:33

US3672203
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:23:55
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User entered 'mmHg'	System	21 Sep 2020 19:41:17
User entered empty.	System	21 Sep 2020 19:40:33

US3672203
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:23:55
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:03:11
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:02:00
User closed query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 19:41:17
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	21 Sep 2020 19:41:17
User entered '91' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 19:41:17
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 19:40:33
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 19:40:33

US3672203
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:23:55
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User entered 'mmHg'	System	21 Sep 2020 19:41:17
User entered empty.	System	21 Sep 2020 19:40:33

US3672203
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:23:55
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	21 Sep 2020 19:40:33

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US3672203
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:23:55
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:11
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:02:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 19:40:33

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US3672203
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:23:55
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:03:11
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:02:00
User closed query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 19:53:29
User entered '18 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 19:53:29
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 19:40:33
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 19:40:33

US3672203
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:23:55
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:03:11
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:02:00
User closed query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 19:53:29
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	21 Sep 2020 19:53:29
User entered '14:00' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 19:53:29
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 19:40:33
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 19:40:33

US3672203
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:23:55
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User entered '18 Sep 2020 14:00'	System	21 Sep 2020 19:53:29
User entered empty.	System	21 Sep 2020 19:40:33

US3672203
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:23:55
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:03:11
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:02:00
User closed query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 19:53:29
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	21 Sep 2020 19:53:29
User entered '98.7' F reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 19:53:29
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 19:40:33
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 19:40:33

US3672203
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:23:55
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:11
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:02:00
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 19:53:29
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 19:40:33

US3672203
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:23:55
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:11
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:02:00
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 19:40:33

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US3672203
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:23:55
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:03:11
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:02:00
User closed query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 19:53:29
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	21 Sep 2020 19:53:29
User entered '70' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 19:53:29
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 19:40:33
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 19:40:33

US3672203
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:23:55
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User entered 'bpm'	System	21 Sep 2020 19:53:29
User entered empty.	System	21 Sep 2020 19:40:33

US3672203
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:23:55
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:03:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:02:00
User closed query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 19:53:29
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	21 Sep 2020 19:53:29
User entered '15' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 19:53:29
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 19:40:33
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 19:40:33

US3672203
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:23:55
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User entered 'breaths/min'	System	21 Sep 2020 19:53:29
User entered empty.	System	21 Sep 2020 19:40:33

US3672203
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:23:55
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:03:11
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:02:00
User closed query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 19:53:29
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	21 Sep 2020 19:53:29
User entered '136' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 19:53:29
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 19:40:33
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 19:40:33

US3672203
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:23:55
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User entered 'mmHg'	System	21 Sep 2020 19:53:29
User entered empty.	System	21 Sep 2020 19:40:33

US3672203
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:23:55
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:03:11
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:02:00
User closed query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 19:53:29
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	21 Sep 2020 19:53:29
User entered '90' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 19:53:29
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 19:40:33
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 19:40:33

US3672203
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:23:55
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User entered 'mmHg'	System	21 Sep 2020 19:53:29
User entered empty.	System	21 Sep 2020 19:40:33

US3672203
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Generated On: 10 Jun 2021 09:23:55
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:13:34
User closed query 'Per source, PE was completed. Please verify and update response to "YES"' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 17:13:31
Query 'Per source, PE was completed. Please verify and update response to "YES"' answered with 'updated per source' (Site from CRA).	(b) (4), (b) (6)	26 Oct 2020 19:25:25
DataPoint Un-verified.	(b) (4), (b) (6)	26 Oct 2020 19:25:14
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Oct 2020 19:25:14
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:03:04
User opened query 'Per source, PE was completed. Please verify and update response to "YES"' (Site from CRA).	(b) (4), (b) (6)	07 Oct 2020 20:02:56
User entered 'No (N)'	(b) (4), (b) (6)	21 Sep 2020 19:53:35

US3672203
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Generated On: 10 Jun 2021 09:23:55
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:11
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 17:13:36
DataPoint Un-verified.	(b) (4), (b) (6)	26 Oct 2020 19:25:14
User entered '18 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Oct 2020 19:25:14
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:02:58
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 19:53:35

FDA-CBER-2022-1614-2944862

US3672203
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:23:55
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:11
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 17:01:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Sep 2020 17:41:32

FDA-CBER-2022-1614-2944863

US3672203
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:23:55
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:11
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 17:01:02
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 17:41:32

US3672203
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:23:55
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)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:11
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 17:01:02
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 17:41:32

US3672203
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:23:55
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User entered 'MRNA-1273 OR PLACEBO'	System	18 Sep 2020 17:41:32

US3672203
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:23:55
What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:11
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 17:01:02
User entered '18 Sep 2020'	(b) (4), (b) (6)	18 Sep 2020 17:41:32

FDA-CBER-2022-1614-2944867

US3672203
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:23:55
What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:11
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 17:01:02
User entered '13:29'	(b) (4), (b) (6)	18 Sep 2020 17:41:32

US3672203
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:23:55
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User entered '18 Sep 2020 13:29'	System	18 Sep 2020 17:41:32

FDA-CBER-2022-1614-2944869

US3672203
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:23:55
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:11
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 17:01:02
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	18 Sep 2020 17:41:32

FDA-CBER-2022-1614-2944870

US3672203
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:23:55
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 17:01:02
User entered 'ONCE'	System	18 Sep 2020 17:41:32

US3672203
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:23:55
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User entered 'INTRAMUSCULAR'	System	18 Sep 2020 17:41:32

US3672203
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:23:55
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:11
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 17:00:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 14:47:26

FDA-CBER-2022-1614-2944873

US3672203
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:23:55
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:11
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 17:00:14
User entered '18 Sep 2020'	(b) (4), (b) (6)	23 Sep 2020 14:47:26

US3672203
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:23:55
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:11
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 17:00:14
User entered '13:05'	(b) (4), (b) (6)	23 Sep 2020 14:47:26

US3672203
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:23:55
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User entered '18 Sep 2020 13:05'	System	23 Sep 2020 14:47:26

US3672203
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab
Generated On: 10 Jun 2021 09:23:55
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:03:11
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 17:00:21
User closed query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' (Site from System).	System	21 Sep 2020 19:54:46
Query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' answered by data change (Site from System).	System	21 Sep 2020 19:54:46
User entered '18 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 19:54:46
User opened query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' (Site from System).	System	21 Sep 2020 19:54:35
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 19:54:35

US3672203
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 09:23:55
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	21 Sep 2020 19:54:35

US3672203
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 09:23:55
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:11
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 17:00:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 19:54:35

US3672203
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 09:23:55
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:11
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 17:00:21
User entered '12:50'	(b) (4), (b) (6)	21 Sep 2020 19:54:35

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US3672203
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 09:23:55
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User entered '18 Sep 2020 12:50'	System	21 Sep 2020 19:54:46
User entered empty.	System	21 Sep 2020 19:54:35

US3672203
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 09:23:55
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	21 Sep 2020 19:54:35

US3672203
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 09:23:55
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:11
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 17:00:21
User entered 'No (N)'	(b) (4), (b) (6)	21 Sep 2020 19:54:35

US3672203
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 09:23:55
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:11
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 17:00:21
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 19:54:35

US3672203
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 09:23:55
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User entered empty.	System	21 Sep 2020 19:54:35

US3672203
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:23:55
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:11
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 17:00:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 19:54:53

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US3672203
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:23:55
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User entered '1'	System	21 Sep 2020 19:54:53

US3672203
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:23:55
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
Data entry locked.	System	18 Sep 2020 17:41:32
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Sep 2020 17:41:32

FDA-CBER-2022-1614-2944888

US3672203
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:23:55
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-18T14:02:00', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: 'c3868c21-97ac-4678-ad9c-8160cf565610'	System	18 Sep 2020 18:02:11
User entered 'Yes (Y)'	System	18 Sep 2020 18:02:11

FDA-CBER-2022-1614-2944889

US3672203
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:23:55
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-18T14:02:03', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: 'c3868c21-97ac-4678-ad9c-8160cf565610'	System	18 Sep 2020 18:02:11
User entered '98.7'	System	18 Sep 2020 18:02:11

FDA-CBER-2022-1614-2944890

US3672203
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:23:55
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-18T14:02:06', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: 'c3868c21-97ac-4678-ad9c-8160cf565610'	System	18 Sep 2020 18:02:11
User entered 'No (N)'	System	18 Sep 2020 18:02:11

FDA-CBER-2022-1614-2944891

US3672203
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:23:55
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-18T14:02:08', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: 'c3868c21-97ac-4678-ad9c-8160cf565610'	System	18 Sep 2020 18:02:11
User entered '18 Sep 2020 14:02'	System	18 Sep 2020 18:02:11

FDA-CBER-2022-1614-2944892

US3672203
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:23:55
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
User entered '18 Sep 2020 13:49'	System	18 Sep 2020 17:41:32

FDA-CBER-2022-1614-2944893

US3672203
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:23:55
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
User entered '18 Sep 2020 16:19'	System	18 Sep 2020 17:41:32

FDA-CBER-2022-1614-2944894

US3672203
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:23:55
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
Data entry locked.	System	18 Sep 2020 17:41:32
User entered 'Day 1, after vaccination (at home)'	System	18 Sep 2020 17:41:32

FDA-CBER-2022-1614-2944895

US3672203
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:23:55
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-18T17:24:27', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '5b025157-78e0-4e7e-b63b-e3dcbf198299'	System	18 Sep 2020 21:24:40
User entered 'Yes (Y)'	System	18 Sep 2020 21:24:40

FDA-CBER-2022-1614-2944896

US3672203
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:23:55
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-18T17:24:31', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '5b025157-78e0-4e7e-b63b-e3dcbf198299'	System	18 Sep 2020 21:24:40
User entered '98.6'	System	18 Sep 2020 21:24:40

FDA-CBER-2022-1614-2944897

US3672203
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:23:55
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-18T17:24:33', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '5b025157-78e0-4e7e-b63b-e3dcbf198299'	System	18 Sep 2020 21:24:40
User entered 'No (N)'	System	18 Sep 2020 21:24:40

FDA-CBER-2022-1614-2944898

US3672203
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:23:55
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-18T17:24:35', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '5b025157-78e0-4e7e-b63b-e3dcbf198299'	System	18 Sep 2020 21:24:40
User entered '18 Sep 2020 17:24'	System	18 Sep 2020 21:24:40

FDA-CBER-2022-1614-2944899

US3672203
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:23:55
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
User entered '18 Sep 2020 17:14'	System	18 Sep 2020 17:41:32

FDA-CBER-2022-1614-2944900

US3672203
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:23:55
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
User entered '19 Sep 2020 11:59'	System	18 Sep 2020 17:41:32

FDA-CBER-2022-1614-2944901

US3672203
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:23:55
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
Data entry locked.	System	18 Sep 2020 17:41:32
User entered 'Day 2'	System	18 Sep 2020 17:41:32

FDA-CBER-2022-1614-2944902

US3672203
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:23:55
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-19T18:00:15', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '9de90fc8-9aa5-47a4-842f-06e261101874'	System	19 Sep 2020 22:00:25
User entered 'Yes (Y)'	System	19 Sep 2020 22:00:25

FDA-CBER-2022-1614-2944903

US3672203
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:23:55
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-19T18:00:19', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '9de90fc8-9aa5-47a4-842f-06e261101874'	System	19 Sep 2020 22:00:25
User entered '98.0'	System	19 Sep 2020 22:00:25

FDA-CBER-2022-1614-2944904

US3672203
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:23:55
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-19T18:00:21', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '9de90fc8-9aa5-47a4-842f-06e261101874'	System	19 Sep 2020 22:00:25
User entered 'No (N)'	System	19 Sep 2020 22:00:25

FDA-CBER-2022-1614-2944905

US3672203
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:23:55
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-19T18:00:23', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '9de90fc8-9aa5-47a4-842f-06e261101874'	System	19 Sep 2020 22:00:25
User entered '19 Sep 2020 18:00'	System	19 Sep 2020 22:00:25

FDA-CBER-2022-1614-2944906

US3672203
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:23:55
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 17:41:32

FDA-CBER-2022-1614-2944907

US3672203
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:23:55
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 17:41:32

FDA-CBER-2022-1614-2944908

US3672203
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:23:55
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
Data entry locked.	System	18 Sep 2020 17:41:32
User entered 'Day 3'	System	18 Sep 2020 17:41:32

US3672203
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:23:55
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-20T19:02:16', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '56451497-890b-4755-9737-70ac114c34c4'	System	20 Sep 2020 23:02:34
User entered 'Yes (Y)'	System	20 Sep 2020 23:02:34

US3672203
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:23:55
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-20T19:02:23', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '56451497-890b-4755-9737-70ac114c34c4'	System	20 Sep 2020 23:02:34
User entered '98.5'	System	20 Sep 2020 23:02:34

FDA-CBER-2022-1614-2944911

US3672203
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:23:55
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-20T19:02:27', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '56451497-890b-4755-9737-70ac114c34c4'	System	20 Sep 2020 23:02:34
User entered 'No (N)'	System	20 Sep 2020 23:02:34

FDA-CBER-2022-1614-2944912

US3672203
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:23:55
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-20T19:02:29', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '56451497-890b-4755-9737-70ac114c34c4'	System	20 Sep 2020 23:02:34
User entered '20 Sep 2020 19:02'	System	20 Sep 2020 23:02:34

FDA-CBER-2022-1614-2944913

US3672203
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:23:55
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
User entered '20 Sep 2020 12:00'	System	18 Sep 2020 17:41:32

FDA-CBER-2022-1614-2944914

US3672203
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:23:55
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
User entered '21 Sep 2020 11:59'	System	18 Sep 2020 17:41:32

FDA-CBER-2022-1614-2944915

US3672203
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:23:55
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
Data entry locked.	System	18 Sep 2020 17:41:32
User entered 'Day 4'	System	18 Sep 2020 17:41:32

US3672203
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:23:55
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-21T16:26:51', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: 'c87d7fdb-84d7-45ba-aa11-3748a4905044'	System	21 Sep 2020 20:27:07
User entered 'Yes (Y)'	System	21 Sep 2020 20:27:07

FDA-CBER-2022-1614-2944917

US3672203
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:23:55
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-21T16:26:55', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: 'c87d7fdb-84d7-45ba-aa11-3748a4905044'	System	21 Sep 2020 20:27:07
User entered '98.8'	System	21 Sep 2020 20:27:07

US3672203
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:23:55
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-21T16:26:58', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: 'c87d7fdb-84d7-45ba-aa11-3748a4905044'	System	21 Sep 2020 20:27:07
User entered 'No (N)'	System	21 Sep 2020 20:27:07

US3672203
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:23:55
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-21T16:27:00', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: 'c87d7fdb-84d7-45ba-aa11-3748a4905044'	System	21 Sep 2020 20:27:07
User entered '21 Sep 2020 16:27'	System	21 Sep 2020 20:27:07

FDA-CBER-2022-1614-2944920

US3672203
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:23:55
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
User entered '21 Sep 2020 12:00'	System	18 Sep 2020 17:41:32

FDA-CBER-2022-1614-2944921

US3672203
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:23:55
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
User entered '22 Sep 2020 11:59'	System	18 Sep 2020 17:41:32

FDA-CBER-2022-1614-2944922

US3672203
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:23:55
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
Data entry locked.	System	18 Sep 2020 17:41:32
User entered 'Day 5'	System	18 Sep 2020 17:41:32

US3672203
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:23:55
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-22T18:37:51', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: 'efc1c153-928e-4aa7-a376-0409ee38d69c'	System	22 Sep 2020 22:38:06
User entered 'Yes (Y)'	System	22 Sep 2020 22:38:06

FDA-CBER-2022-1614-2944924

US3672203
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:23:55
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-22T18:37:54', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: 'efc1c153-928e-4aa7-a376-0409ee38d69c'	System	22 Sep 2020 22:38:06
User entered '98.9'	System	22 Sep 2020 22:38:06

FDA-CBER-2022-1614-2944925

US3672203
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:23:55
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-22T18:37:58', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: 'efc1c153-928e-4aa7-a376-0409ee38d69c'	System	22 Sep 2020 22:38:06
User entered 'No (N)'	System	22 Sep 2020 22:38:06

FDA-CBER-2022-1614-2944926

US3672203
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:23:55
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-22T18:38:02', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: 'efc1c153-928e-4aa7-a376-0409ee38d69c'	System	22 Sep 2020 22:38:06
User entered '22 Sep 2020 18:38'	System	22 Sep 2020 22:38:06

FDA-CBER-2022-1614-2944927

US3672203
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:23:55
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
User entered '22 Sep 2020 12:00'	System	18 Sep 2020 17:41:32

FDA-CBER-2022-1614-2944928

US3672203
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:23:55
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
User entered '23 Sep 2020 11:59'	System	18 Sep 2020 17:41:32

FDA-CBER-2022-1614-2944929

US3672203
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:23:55
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
Data entry locked.	System	18 Sep 2020 17:41:32
User entered 'Day 6'	System	18 Sep 2020 17:41:32

US3672203
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:23:55
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-23T18:56:21', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: 'b1a454ac-6540-40ca-896f-6d004d62e06a'	System	23 Sep 2020 22:56:35
User entered 'Yes (Y)'	System	23 Sep 2020 22:56:35

FDA-CBER-2022-1614-2944931

US3672203
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:23:55
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-23T18:56:24', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: 'b1a454ac-6540-40ca-896f-6d004d62e06a'	System	23 Sep 2020 22:56:35
User entered '98.6'	System	23 Sep 2020 22:56:35

FDA-CBER-2022-1614-2944932

US3672203
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:23:55
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-23T18:56:26', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: 'b1a454ac-6540-40ca-896f-6d004d62e06a'	System	23 Sep 2020 22:56:35
User entered 'No (N)'	System	23 Sep 2020 22:56:35

US3672203
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:23:55
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-23T18:56:28', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: 'b1a454ac-6540-40ca-896f-6d004d62e06a'	System	23 Sep 2020 22:56:35
User entered '23 Sep 2020 18:56'	System	23 Sep 2020 22:56:35

FDA-CBER-2022-1614-2944934

US3672203
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:23:55
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
User entered '23 Sep 2020 12:00'	System	18 Sep 2020 17:41:32

FDA-CBER-2022-1614-2944935

US3672203
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:23:55
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
User entered '24 Sep 2020 11:59'	System	18 Sep 2020 17:41:32

FDA-CBER-2022-1614-2944936

US3672203
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:23:55
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
Data entry locked.	System	18 Sep 2020 17:41:32
User entered 'Day 7'	System	18 Sep 2020 17:41:32

US3672203
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:23:55
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-24T21:57:21', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: 'ba1143d1-5727-4205-bd3c-1541a31eb639'	System	25 Sep 2020 01:57:40
User entered 'Yes (Y)'	System	25 Sep 2020 01:57:40

FDA-CBER-2022-1614-2944938

US3672203
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:23:55
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-24T21:57:29', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: 'ba1143d1-5727-4205-bd3c-1541a31eb639'	System	25 Sep 2020 01:57:40
User entered '98.7'	System	25 Sep 2020 01:57:40

FDA-CBER-2022-1614-2944939

US3672203
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:23:55
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-24T21:57:37', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: 'ba1143d1-5727-4205-bd3c-1541a31eb639'	System	25 Sep 2020 01:57:40
User entered 'No (N)'	System	25 Sep 2020 01:57:40

FDA-CBER-2022-1614-2944940

US3672203
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:23:55
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-24T21:57:39', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: 'ba1143d1-5727-4205-bd3c-1541a31eb639'	System	25 Sep 2020 01:57:40
User entered '24 Sep 2020 21:57'	System	25 Sep 2020 01:57:40

FDA-CBER-2022-1614-2944941

US3672203
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:23:55
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
User entered '24 Sep 2020 12:00'	System	18 Sep 2020 17:41:32

FDA-CBER-2022-1614-2944942

US3672203
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:23:55
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
User entered '25 Sep 2020 11:59'	System	18 Sep 2020 17:41:32

FDA-CBER-2022-1614-2944943

US3672203
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:23:55
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
Data entry locked.	System	18 Sep 2020 17:41:32
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Sep 2020 17:41:32

FDA-CBER-2022-1614-2944944

US3672203
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:23:55
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 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-18T14:02:11', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '6b48cffd-ed60-4a54-be77-ef58a3edafb5'	System	18 Sep 2020 18:02:20
User entered 'None (1)'	System	18 Sep 2020 18:02:20

FDA-CBER-2022-1614-2944945

US3672203
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:23:55
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-18T14:02:12', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '6b48cffd-ed60-4a54-be77-ef58a3edafb5'	System	18 Sep 2020 18:02:20
User entered 'No (N)'	System	18 Sep 2020 18:02:20

FDA-CBER-2022-1614-2944946

US3672203
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:23:55
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-18T14:02:14', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '6b48cffd-ed60-4a54-be77-ef58a3edafb5'	System	18 Sep 2020 18:02:20
User entered 'No (N)'	System	18 Sep 2020 18:02:20

FDA-CBER-2022-1614-2944947

US3672203
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:23:55
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 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-18T14:02:15', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '6b48cffd-ed60-4a54-be77-ef58a3edafb5'	System	18 Sep 2020 18:02:20
User entered 'None (1)'	System	18 Sep 2020 18:02:20

FDA-CBER-2022-1614-2944948

US3672203
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:23:55
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-18T14:02:17', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '6b48cffd-ed60-4a54-be77-ef58a3edafb5'	System	18 Sep 2020 18:02:20
User entered '18 Sep 2020 14:02'	System	18 Sep 2020 18:02:20

FDA-CBER-2022-1614-2944949

US3672203
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:23:55
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
User entered '18 Sep 2020 13:49'	System	18 Sep 2020 17:41:32

FDA-CBER-2022-1614-2944950

US3672203
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:23:55
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
User entered '18 Sep 2020 16:19'	System	18 Sep 2020 17:41:32

FDA-CBER-2022-1614-2944951

US3672203
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:23:55
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
Data entry locked.	System	18 Sep 2020 17:41:32
User entered 'Day 1, after vaccination (at home)'	System	18 Sep 2020 17:41:32

US3672203
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:23:55
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 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-18T17:24:39', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: 'fd9ce7cc-dcf4-4208-b409-cb515e34dc8d'	System	18 Sep 2020 21:25:02
User entered 'None (1)'	System	18 Sep 2020 21:25:02

FDA-CBER-2022-1614-2944953

US3672203
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:23:55
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-18T17:24:52', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: 'fd9ce7cc-dcf4-4208-b409-cb515e34dc8d'	System	18 Sep 2020 21:25:02
User entered 'No (N)'	System	18 Sep 2020 21:25:02

FDA-CBER-2022-1614-2944954

US3672203
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:23:55
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-18T17:24:56', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: 'fd9ce7cc-dcf4-4208-b409-cb515e34dc8d'	System	18 Sep 2020 21:25:02
User entered 'No (N)'	System	18 Sep 2020 21:25:02

FDA-CBER-2022-1614-2944955

US3672203
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:23:55
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 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-18T17:24:58', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: 'fd9ce7cc-dcf4-4208-b409-cb515e34dc8d'	System	18 Sep 2020 21:25:02
User entered 'None (1)'	System	18 Sep 2020 21:25:02

FDA-CBER-2022-1614-2944956

US3672203
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:23:55
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-18T17:25:01', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: 'fd9ce7cc-dcf4-4208-b409-cb515e34dc8d'	System	18 Sep 2020 21:25:02
User entered '18 Sep 2020 17:25'	System	18 Sep 2020 21:25:02

FDA-CBER-2022-1614-2944957

US3672203
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:23:55
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
User entered '18 Sep 2020 17:14'	System	18 Sep 2020 17:41:32

FDA-CBER-2022-1614-2944958

US3672203
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:23:55
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
User entered '19 Sep 2020 11:59'	System	18 Sep 2020 17:41:32

FDA-CBER-2022-1614-2944959

US3672203
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:23:55
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
Data entry locked.	System	18 Sep 2020 17:41:32
User entered 'Day 2'	System	18 Sep 2020 17:41:32

FDA-CBER-2022-1614-2944960

US3672203
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:23:55
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 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-19T17:59:46', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: 'f4cab5aa-5094-43aa-896e-3266bfc27eb2'	System	19 Sep 2020 21:59:56
User entered 'None (1)'	System	19 Sep 2020 21:59:56

FDA-CBER-2022-1614-2944961

US3672203
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:23:55
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-19T17:59:48', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: 'f4cab5aa-5094-43aa-896e-3266bfc27eb2'	System	19 Sep 2020 21:59:56
User entered 'No (N)'	System	19 Sep 2020 21:59:56

FDA-CBER-2022-1614-2944962

US3672203
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:23:55
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-19T17:59:49', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: 'f4cab5aa-5094-43aa-896e-3266bfc27eb2'	System	19 Sep 2020 21:59:56
User entered 'No (N)'	System	19 Sep 2020 21:59:56

US3672203
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:23:55
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 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-19T17:59:50', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: 'f4cab5aa-5094-43aa-896e-3266bfc27eb2'	System	19 Sep 2020 21:59:56
User entered 'None (1)'	System	19 Sep 2020 21:59:56

FDA-CBER-2022-1614-2944964

US3672203
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:23:55
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-19T17:59:52', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: 'f4cab5aa-5094-43aa-896e-3266bfc27eb2'	System	19 Sep 2020 21:59:56
User entered '19 Sep 2020 17:59'	System	19 Sep 2020 21:59:56

FDA-CBER-2022-1614-2944965

US3672203
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:23:55
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 17:41:32

FDA-CBER-2022-1614-2944966

US3672203
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:23:55
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 17:41:32

FDA-CBER-2022-1614-2944967

US3672203
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:23:55
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
Data entry locked.	System	18 Sep 2020 17:41:32
User entered 'Day 3'	System	18 Sep 2020 17:41:32

FDA-CBER-2022-1614-2944968

US3672203
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:23:55
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 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-20T19:02:32', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: 'e328d4c7-c4b1-4bc4-ba28-35f54b2b5472'	System	20 Sep 2020 23:02:40
User entered 'None (1)'	System	20 Sep 2020 23:02:40

FDA-CBER-2022-1614-2944969

US3672203
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:23:55
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-20T19:02:34', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: 'e328d4c7-c4b1-4bc4-ba28-35f54b2b5472'	System	20 Sep 2020 23:02:40
User entered 'No (N)'	System	20 Sep 2020 23:02:40

US3672203
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:23:55
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-20T19:02:35', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: 'e328d4c7-c4b1-4bc4-ba28-35f54b2b5472'	System	20 Sep 2020 23:02:40
User entered 'No (N)'	System	20 Sep 2020 23:02:40

FDA-CBER-2022-1614-2944971

US3672203
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:23:55
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 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-20T19:02:37', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: 'e328d4c7-c4b1-4bc4-ba28-35f54b2b5472'	System	20 Sep 2020 23:02:40
User entered 'None (1)'	System	20 Sep 2020 23:02:40

FDA-CBER-2022-1614-2944972

US3672203
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:23:55
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-20T19:02:39', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: 'e328d4c7-c4b1-4bc4-ba28-35f54b2b5472'	System	20 Sep 2020 23:02:40
User entered '20 Sep 2020 19:02'	System	20 Sep 2020 23:02:40

FDA-CBER-2022-1614-2944973

US3672203
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:23:55
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
User entered '20 Sep 2020 12:00'	System	18 Sep 2020 17:41:32

FDA-CBER-2022-1614-2944974

US3672203
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:23:55
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
User entered '21 Sep 2020 11:59'	System	18 Sep 2020 17:41:32

FDA-CBER-2022-1614-2944975

US3672203
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:23:55
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
Data entry locked.	System	18 Sep 2020 17:41:32
User entered 'Day 4'	System	18 Sep 2020 17:41:32

FDA-CBER-2022-1614-2944976

US3672203
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:23:55
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 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-21T16:27:04', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '28820072-504a-4e17-abae-56cbf119c8ac'	System	21 Sep 2020 20:27:15
User entered 'None (1)'	System	21 Sep 2020 20:27:15

FDA-CBER-2022-1614-2944977

US3672203
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:23:55
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-21T16:27:07', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '28820072-504a-4e17-abae-56cbf119c8ac'	System	21 Sep 2020 20:27:15
User entered 'No (N)'	System	21 Sep 2020 20:27:15

FDA-CBER-2022-1614-2944978

US3672203
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:23:55
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-21T16:27:09', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '28820072-504a-4e17-abae-56cbf119c8ac'	System	21 Sep 2020 20:27:15
User entered 'No (N)'	System	21 Sep 2020 20:27:15

FDA-CBER-2022-1614-2944979

US3672203
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:23:55
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 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-21T16:27:11', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '28820072-504a-4e17-abae-56cbf119c8ac'	System	21 Sep 2020 20:27:15
User entered 'None (1)'	System	21 Sep 2020 20:27:15

FDA-CBER-2022-1614-2944980

US3672203
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:23:55
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-21T16:27:13', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '28820072-504a-4e17-abae-56cbf119c8ac'	System	21 Sep 2020 20:27:15
User entered '21 Sep 2020 16:27'	System	21 Sep 2020 20:27:15

FDA-CBER-2022-1614-2944981

US3672203
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:23:55
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
User entered '21 Sep 2020 12:00'	System	18 Sep 2020 17:41:32

FDA-CBER-2022-1614-2944982

US3672203
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:23:55
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
User entered '22 Sep 2020 11:59'	System	18 Sep 2020 17:41:32

FDA-CBER-2022-1614-2944983

US3672203
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:23:55
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
Data entry locked.	System	18 Sep 2020 17:41:32
User entered 'Day 5'	System	18 Sep 2020 17:41:32

US3672203
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:23:55
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 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-22T18:38:24', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: 'fd943940-2c82-4af8-8218-dcfd0f96c35a'	System	22 Sep 2020 22:39:05
User entered 'None (1)'	System	22 Sep 2020 22:39:05

FDA-CBER-2022-1614-2944985

US3672203
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:23:55
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-22T18:38:57', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: 'fd943940-2c82-4af8-8218-dcfd0f96c35a'	System	22 Sep 2020 22:39:05
User entered 'No (N)'	System	22 Sep 2020 22:39:05

FDA-CBER-2022-1614-2944986

US3672203
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:23:55
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-22T18:38:59', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: 'fd943940-2c82-4af8-8218-dcfd0f96c35a'	System	22 Sep 2020 22:39:05
User entered 'No (N)'	System	22 Sep 2020 22:39:05

US3672203
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:23:55
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 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-22T18:39:01', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: 'fd943940-2c82-4af8-8218-dcfd0f96c35a'	System	22 Sep 2020 22:39:05
User entered 'None (1)'	System	22 Sep 2020 22:39:05

FDA-CBER-2022-1614-2944988

US3672203
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:23:55
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-22T18:39:03', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: 'fd943940-2c82-4af8-8218-dcfd0f96c35a'	System	22 Sep 2020 22:39:05
User entered '22 Sep 2020 18:39'	System	22 Sep 2020 22:39:05

US3672203
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:23:55
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
User entered '22 Sep 2020 12:00'	System	18 Sep 2020 17:41:32

FDA-CBER-2022-1614-2944990

US3672203
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:23:55
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
User entered '23 Sep 2020 11:59'	System	18 Sep 2020 17:41:32

FDA-CBER-2022-1614-2944991

US3672203
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:23:55
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
Data entry locked.	System	18 Sep 2020 17:41:32
User entered 'Day 6'	System	18 Sep 2020 17:41:32

US3672203
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:23:55
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 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-23T18:56:31', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '0d264c58-910d-49f2-98f2-d9c66682eb30'	System	23 Sep 2020 22:56:39
User entered 'None (1)'	System	23 Sep 2020 22:56:39

FDA-CBER-2022-1614-2944993

US3672203
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:23:55
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-23T18:56:32', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '0d264c58-910d-49f2-98f2-d9c66682eb30'	System	23 Sep 2020 22:56:39
User entered 'No (N)'	System	23 Sep 2020 22:56:39

FDA-CBER-2022-1614-2944994

US3672203
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:23:55
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-23T18:56:34', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '0d264c58-910d-49f2-98f2-d9c66682eb30'	System	23 Sep 2020 22:56:39
User entered 'No (N)'	System	23 Sep 2020 22:56:39

FDA-CBER-2022-1614-2944995

US3672203
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:23:55
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 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-23T18:56:35', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '0d264c58-910d-49f2-98f2-d9c66682eb30'	System	23 Sep 2020 22:56:39
User entered 'None (1)'	System	23 Sep 2020 22:56:39

FDA-CBER-2022-1614-2944996

US3672203
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:23:55
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-23T18:56:36', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '0d264c58-910d-49f2-98f2-d9c66682eb30'	System	23 Sep 2020 22:56:39
User entered '23 Sep 2020 18:56'	System	23 Sep 2020 22:56:39

FDA-CBER-2022-1614-2944997

US3672203
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:23:55
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
User entered '23 Sep 2020 12:00'	System	18 Sep 2020 17:41:32

FDA-CBER-2022-1614-2944998

US3672203
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:23:55
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
User entered '24 Sep 2020 11:59'	System	18 Sep 2020 17:41:32

FDA-CBER-2022-1614-2944999

US3672203
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:23:55
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
Data entry locked.	System	18 Sep 2020 17:41:32
User entered 'Day 7'	System	18 Sep 2020 17:41:32

US3672203
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:23:55
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 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-24T21:57:41', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '2c34e71c-aaf4-4fcd-86a5-3d8843c9e7ea'	System	25 Sep 2020 01:57:53
User entered 'None (1)'	System	25 Sep 2020 01:57:53

FDA-CBER-2022-1614-2945001

US3672203
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:23:55
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-24T21:57:43', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '2c34e71c-aaf4-4fcd-86a5-3d8843c9e7ea'	System	25 Sep 2020 01:57:53
User entered 'No (N)'	System	25 Sep 2020 01:57:53

FDA-CBER-2022-1614-2945002

US3672203
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:23:55
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-24T21:57:45', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '2c34e71c-aaf4-4fcd-86a5-3d8843c9e7ea'	System	25 Sep 2020 01:57:53
User entered 'No (N)'	System	25 Sep 2020 01:57:53

FDA-CBER-2022-1614-2945003

US3672203
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:23:55
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 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-24T21:57:46', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '2c34e71c-aaf4-4fcd-86a5-3d8843c9e7ea'	System	25 Sep 2020 01:57:53
User entered 'None (1)'	System	25 Sep 2020 01:57:53

FDA-CBER-2022-1614-2945004

US3672203
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:23:55
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-24T21:57:48', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '2c34e71c-aaf4-4fcd-86a5-3d8843c9e7ea'	System	25 Sep 2020 01:57:53
User entered '24 Sep 2020 21:57'	System	25 Sep 2020 01:57:53

FDA-CBER-2022-1614-2945005

US3672203
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:23:55
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
User entered '24 Sep 2020 12:00'	System	18 Sep 2020 17:41:32

FDA-CBER-2022-1614-2945006

US3672203
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:23:55
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
User entered '25 Sep 2020 11:59'	System	18 Sep 2020 17:41:32

FDA-CBER-2022-1614-2945007

US3672203
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:23:55
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
Data entry locked.	System	18 Sep 2020 17:41:32
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Sep 2020 17:41:32

US3672203
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:23:55
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-18T14:01:39', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: 'f15ec97f-d497-44fc-a627-986f39f2d578'	System	18 Sep 2020 18:01:59
User entered 'None (0)'	System	18 Sep 2020 18:01:59

FDA-CBER-2022-1614-2945009

US3672203
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:23:55
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-18T14:01:41', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: 'f15ec97f-d497-44fc-a627-986f39f2d578'	System	18 Sep 2020 18:01:59
User entered 'None (0)'	System	18 Sep 2020 18:01:59

FDA-CBER-2022-1614-2945010

US3672203
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:23:55
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-18T14:01:47', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: 'f15ec97f-d497-44fc-a627-986f39f2d578'	System	18 Sep 2020 18:01:59
User entered 'None (0)'	System	18 Sep 2020 18:01:59

FDA-CBER-2022-1614-2945011

US3672203
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:23:55
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-18T14:01:49', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: 'f15ec97f-d497-44fc-a627-986f39f2d578'	System	18 Sep 2020 18:01:59
User entered 'None (0)'	System	18 Sep 2020 18:01:59

FDA-CBER-2022-1614-2945012

US3672203
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:23:55
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-18T14:01:50', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: 'f15ec97f-d497-44fc-a627-986f39f2d578'	System	18 Sep 2020 18:01:59
User entered 'None (0)'	System	18 Sep 2020 18:01:59

FDA-CBER-2022-1614-2945013

US3672203
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:23:55
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-18T14:01:51', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: 'f15ec97f-d497-44fc-a627-986f39f2d578'	System	18 Sep 2020 18:01:59
User entered 'None (0)'	System	18 Sep 2020 18:01:59

FDA-CBER-2022-1614-2945014

US3672203
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:23:55
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 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-18T14:01:54', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: 'f15ec97f-d497-44fc-a627-986f39f2d578'	System	18 Sep 2020 18:01:59
User entered 'No (N)'	System	18 Sep 2020 18:01:59

FDA-CBER-2022-1614-2945015

US3672203
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:23:55
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-18T14:01:56', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: 'f15ec97f-d497-44fc-a627-986f39f2d578'	System	18 Sep 2020 18:01:59
User entered '18 Sep 2020 14:01'	System	18 Sep 2020 18:01:59

FDA-CBER-2022-1614-2945016

US3672203
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:23:55
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
User entered '18 Sep 2020 13:49'	System	18 Sep 2020 17:41:32

FDA-CBER-2022-1614-2945017

US3672203
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:23:55
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
User entered '18 Sep 2020 16:19'	System	18 Sep 2020 17:41:32

FDA-CBER-2022-1614-2945018

US3672203
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:23:55
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
Data entry locked.	System	18 Sep 2020 17:41:32
User entered 'Day 1, after vaccination (at home)'	System	18 Sep 2020 17:41:32

US3672203
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:23:55
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-18T17:25:04', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '55d40c9a-2669-4bc9-ad51-ba9e426286aa'	System	18 Sep 2020 21:25:26
User entered 'None (0)'	System	18 Sep 2020 21:25:26

FDA-CBER-2022-1614-2945020

US3672203
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:23:55
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-18T17:25:05', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '55d40c9a-2669-4bc9-ad51-ba9e426286aa'	System	18 Sep 2020 21:25:26
User entered 'None (0)'	System	18 Sep 2020 21:25:26

FDA-CBER-2022-1614-2945021

US3672203
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:23:55
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-18T17:25:07', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '55d40c9a-2669-4bc9-ad51-ba9e426286aa'	System	18 Sep 2020 21:25:26
User entered 'None (0)'	System	18 Sep 2020 21:25:26

FDA-CBER-2022-1614-2945022

US3672203
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:23:55
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-18T17:25:08', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '55d40c9a-2669-4bc9-ad51-ba9e426286aa'	System	18 Sep 2020 21:25:26
User entered 'None (0)'	System	18 Sep 2020 21:25:26

FDA-CBER-2022-1614-2945023

US3672203
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:23:55
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-18T17:25:10', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '55d40c9a-2669-4bc9-ad51-ba9e426286aa'	System	18 Sep 2020 21:25:26
User entered 'None (0)'	System	18 Sep 2020 21:25:26

FDA-CBER-2022-1614-2945024

US3672203
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:23:55
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-18T17:25:11', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '55d40c9a-2669-4bc9-ad51-ba9e426286aa'	System	18 Sep 2020 21:25:26
User entered 'None (0)'	System	18 Sep 2020 21:25:26

FDA-CBER-2022-1614-2945025

US3672203
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:23:55
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 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-18T17:25:20', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '55d40c9a-2669-4bc9-ad51-ba9e426286aa'	System	18 Sep 2020 21:25:26
User entered 'No (N)'	System	18 Sep 2020 21:25:26

FDA-CBER-2022-1614-2945026

US3672203
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:23:55
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-18T17:25:22', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '55d40c9a-2669-4bc9-ad51-ba9e426286aa'	System	18 Sep 2020 21:25:26
User entered '18 Sep 2020 17:25'	System	18 Sep 2020 21:25:26

FDA-CBER-2022-1614-2945027

US3672203
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:23:55
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
User entered '18 Sep 2020 17:14'	System	18 Sep 2020 17:41:32

FDA-CBER-2022-1614-2945028

US3672203
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:23:55
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
User entered '19 Sep 2020 11:59'	System	18 Sep 2020 17:41:32

FDA-CBER-2022-1614-2945029

US3672203
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:23:55
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
Data entry locked.	System	18 Sep 2020 17:41:32
User entered 'Day 2'	System	18 Sep 2020 17:41:32

US3672203
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:23:55
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-19T17:59:56', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '6f20f252-ecf1-4910-acdf-aaa2b969b08a'	System	19 Sep 2020 22:00:12
User entered 'None (0)'	System	19 Sep 2020 22:00:12

FDA-CBER-2022-1614-2945031

US3672203
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:23:55
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-19T17:59:58', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '6f20f252-ecf1-4910-acdf-aaa2b969b08a'	System	19 Sep 2020 22:00:12
User entered 'None (0)'	System	19 Sep 2020 22:00:12

US3672203
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:23:55
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-19T18:00:00', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '6f20f252-ecf1-4910-acdf-aaa2b969b08a'	System	19 Sep 2020 22:00:12
User entered 'None (0)'	System	19 Sep 2020 22:00:12

FDA-CBER-2022-1614-2945033

US3672203
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:23:55
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-19T18:00:03', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '6f20f252-ecf1-4910-acdf-aaa2b969b08a'	System	19 Sep 2020 22:00:12
User entered 'None (0)'	System	19 Sep 2020 22:00:12

FDA-CBER-2022-1614-2945034

US3672203
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:23:55
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-19T18:00:04', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '6f20f252-ecf1-4910-acdf-aaa2b969b08a'	System	19 Sep 2020 22:00:12
User entered 'None (0)'	System	19 Sep 2020 22:00:12

FDA-CBER-2022-1614-2945035

US3672203
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:23:55
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-19T18:00:06', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '6f20f252-ecf1-4910-acdf-aaa2b969b08a'	System	19 Sep 2020 22:00:12
User entered 'None (0)'	System	19 Sep 2020 22:00:12

FDA-CBER-2022-1614-2945036

US3672203
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:23:55
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 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-19T18:00:09', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '6f20f252-ecf1-4910-acdf-aaa2b969b08a'	System	19 Sep 2020 22:00:12
User entered 'No (N)'	System	19 Sep 2020 22:00:12

US3672203
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:23:55
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-19T18:00:10', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '6f20f252-ecf1-4910-acdf-aaa2b969b08a'	System	19 Sep 2020 22:00:12
User entered '19 Sep 2020 18:00'	System	19 Sep 2020 22:00:12

FDA-CBER-2022-1614-2945038

US3672203
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:23:55
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 17:41:32

US3672203
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:23:55
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 17:41:32

FDA-CBER-2022-1614-2945040

US3672203
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:23:55
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
Data entry locked.	System	18 Sep 2020 17:41:32
User entered 'Day 3'	System	18 Sep 2020 17:41:32

US3672203
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:23:55
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-20T19:02:42', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '828d2336-179d-44aa-bcaf-4edc36f78c62'	System	20 Sep 2020 23:03:00
User entered 'None (0)'	System	20 Sep 2020 23:03:00

US3672203
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:23:55
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-20T19:02:44', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '828d2336-179d-44aa-bcaf-4edc36f78c62'	System	20 Sep 2020 23:03:00
User entered 'None (0)'	System	20 Sep 2020 23:03:00

US3672203
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:23:55
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-20T19:02:46', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '828d2336-179d-44aa-bcaf-4edc36f78c62'	System	20 Sep 2020 23:03:00
User entered 'None (0)'	System	20 Sep 2020 23:03:00

FDA-CBER-2022-1614-2945044

US3672203
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:23:55
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-20T19:02:47', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '828d2336-179d-44aa-bcaf-4edc36f78c62'	System	20 Sep 2020 23:03:00
User entered 'None (0)'	System	20 Sep 2020 23:03:00

FDA-CBER-2022-1614-2945045

US3672203
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:23:55
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-20T19:02:49', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '828d2336-179d-44aa-bcaf-4edc36f78c62'	System	20 Sep 2020 23:03:00
User entered 'None (0)'	System	20 Sep 2020 23:03:00

FDA-CBER-2022-1614-2945046

US3672203
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:23:55
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-20T19:02:50', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '828d2336-179d-44aa-bcaf-4edc36f78c62'	System	20 Sep 2020 23:03:00
User entered 'None (0)'	System	20 Sep 2020 23:03:00

US3672203
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:23:55
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 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-20T19:02:55', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '828d2336-179d-44aa-bcaf-4edc36f78c62'	System	20 Sep 2020 23:03:00
User entered 'No (N)'	System	20 Sep 2020 23:03:00

US3672203
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:23:55
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-20T19:02:58', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '828d2336-179d-44aa-bcaf-4edc36f78c62'	System	20 Sep 2020 23:03:00
User entered '20 Sep 2020 19:02'	System	20 Sep 2020 23:03:00

US3672203
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:23:55
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
User entered '20 Sep 2020 12:00'	System	18 Sep 2020 17:41:32

US3672203
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:23:55
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
User entered '21 Sep 2020 11:59'	System	18 Sep 2020 17:41:32

FDA-CBER-2022-1614-2945051

US3672203
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:23:55
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
Data entry locked.	System	18 Sep 2020 17:41:32
User entered 'Day 4'	System	18 Sep 2020 17:41:32

US3672203
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:23:55
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-21T16:27:17', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '2838a62d-8663-47c2-b878-89d5edce2069'	System	21 Sep 2020 20:27:33
User entered 'None (0)'	System	21 Sep 2020 20:27:33

US3672203
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:23:55
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-21T16:27:19', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '2838a62d-8663-47c2-b878-89d5edce2069'	System	21 Sep 2020 20:27:33
User entered 'None (0)'	System	21 Sep 2020 20:27:33

US3672203
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:23:55
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-21T16:27:21', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '2838a62d-8663-47c2-b878-89d5edce2069'	System	21 Sep 2020 20:27:33
User entered 'None (0)'	System	21 Sep 2020 20:27:33

FDA-CBER-2022-1614-2945055

US3672203
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:23:55
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-21T16:27:23', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '2838a62d-8663-47c2-b878-89d5edce2069'	System	21 Sep 2020 20:27:33
User entered 'None (0)'	System	21 Sep 2020 20:27:33

FDA-CBER-2022-1614-2945056

US3672203
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:23:55
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-21T16:27:24', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '2838a62d-8663-47c2-b878-89d5edce2069'	System	21 Sep 2020 20:27:33
User entered 'None (0)'	System	21 Sep 2020 20:27:33

FDA-CBER-2022-1614-2945057

US3672203
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:23:55
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-21T16:27:26', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '2838a62d-8663-47c2-b878-89d5edce2069'	System	21 Sep 2020 20:27:33
User entered 'None (0)'	System	21 Sep 2020 20:27:33

US3672203
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:23:55
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 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-21T16:27:30', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '2838a62d-8663-47c2-b878-89d5edce2069'	System	21 Sep 2020 20:27:33
User entered 'No (N)'	System	21 Sep 2020 20:27:33

FDA-CBER-2022-1614-2945059

US3672203
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:23:55
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-21T16:27:32', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '2838a62d-8663-47c2-b878-89d5edce2069'	System	21 Sep 2020 20:27:33
User entered '21 Sep 2020 16:27'	System	21 Sep 2020 20:27:33

FDA-CBER-2022-1614-2945060

US3672203
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:23:55
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
User entered '21 Sep 2020 12:00'	System	18 Sep 2020 17:41:32

FDA-CBER-2022-1614-2945061

US3672203
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:23:55
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
User entered '22 Sep 2020 11:59'	System	18 Sep 2020 17:41:32

FDA-CBER-2022-1614-2945062

US3672203
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:23:55
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
Data entry locked.	System	18 Sep 2020 17:41:32
User entered 'Day 5'	System	18 Sep 2020 17:41:32

US3672203
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:23:55
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-22T18:39:05', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '72b07540-2d30-44f1-b09a-20c742f38fc4'	System	22 Sep 2020 22:39:21
User entered 'None (0)'	System	22 Sep 2020 22:39:21

FDA-CBER-2022-1614-2945064

US3672203
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:23:55
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-22T18:39:07', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '72b07540-2d30-44f1-b09a-20c742f38fc4'	System	22 Sep 2020 22:39:21
User entered 'None (0)'	System	22 Sep 2020 22:39:21

US3672203
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:23:55
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-22T18:39:08', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '72b07540-2d30-44f1-b09a-20c742f38fc4'	System	22 Sep 2020 22:39:21
User entered 'None (0)'	System	22 Sep 2020 22:39:21

FDA-CBER-2022-1614-2945066

US3672203
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:23:55
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-22T18:39:10', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '72b07540-2d30-44f1-b09a-20c742f38fc4'	System	22 Sep 2020 22:39:21
User entered 'None (0)'	System	22 Sep 2020 22:39:21

FDA-CBER-2022-1614-2945067

US3672203
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:23:55
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-22T18:39:13', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '72b07540-2d30-44f1-b09a-20c742f38fc4'	System	22 Sep 2020 22:39:21
User entered 'None (0)'	System	22 Sep 2020 22:39:21

US3672203
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:23:55
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-22T18:39:14', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '72b07540-2d30-44f1-b09a-20c742f38fc4'	System	22 Sep 2020 22:39:21
User entered 'None (0)'	System	22 Sep 2020 22:39:21

US3672203
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:23:55
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 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-22T18:39:16', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '72b07540-2d30-44f1-b09a-20c742f38fc4'	System	22 Sep 2020 22:39:21
User entered 'No (N)'	System	22 Sep 2020 22:39:21

US3672203
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:23:55
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-22T18:39:18', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '72b07540-2d30-44f1-b09a-20c742f38fc4'	System	22 Sep 2020 22:39:21
User entered '22 Sep 2020 18:39'	System	22 Sep 2020 22:39:21

FDA-CBER-2022-1614-2945071

US3672203
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:23:55
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
User entered '22 Sep 2020 12:00'	System	18 Sep 2020 17:41:32

US3672203
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:23:55
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
User entered '23 Sep 2020 11:59'	System	18 Sep 2020 17:41:32

FDA-CBER-2022-1614-2945073

US3672203
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:23:55
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
Data entry locked.	System	18 Sep 2020 17:41:32
User entered 'Day 6'	System	18 Sep 2020 17:41:32

US3672203
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:23:55
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-23T18:56:39', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: 'a9c66486-186c-4dd0-b653-7164d55b02e4'	System	23 Sep 2020 22:56:50
User entered 'None (0)'	System	23 Sep 2020 22:56:50

FDA-CBER-2022-1614-2945075

US3672203
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:23:55
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-23T18:56:41', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: 'a9c66486-186c-4dd0-b653-7164d55b02e4'	System	23 Sep 2020 22:56:50
User entered 'None (0)'	System	23 Sep 2020 22:56:50

FDA-CBER-2022-1614-2945076

US3672203
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:23:55
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-23T18:56:42', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: 'a9c66486-186c-4dd0-b653-7164d55b02e4'	System	23 Sep 2020 22:56:50
User entered 'None (0)'	System	23 Sep 2020 22:56:50

FDA-CBER-2022-1614-2945077

US3672203
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:23:55
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-23T18:56:43', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: 'a9c66486-186c-4dd0-b653-7164d55b02e4'	System	23 Sep 2020 22:56:50
User entered 'None (0)'	System	23 Sep 2020 22:56:50

FDA-CBER-2022-1614-2945078

US3672203
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:23:55
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-23T18:56:44', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: 'a9c66486-186c-4dd0-b653-7164d55b02e4'	System	23 Sep 2020 22:56:50
User entered 'None (0)'	System	23 Sep 2020 22:56:50

US3672203
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:23:55
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-23T18:56:45', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: 'a9c66486-186c-4dd0-b653-7164d55b02e4'	System	23 Sep 2020 22:56:50
User entered 'None (0)'	System	23 Sep 2020 22:56:50

US3672203
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:23:55
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 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-23T18:56:47', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: 'a9c66486-186c-4dd0-b653-7164d55b02e4'	System	23 Sep 2020 22:56:50
User entered 'No (N)'	System	23 Sep 2020 22:56:50

FDA-CBER-2022-1614-2945081

US3672203
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:23:55
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-23T18:56:49', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: 'a9c66486-186c-4dd0-b653-7164d55b02e4'	System	23 Sep 2020 22:56:50
User entered '23 Sep 2020 18:56'	System	23 Sep 2020 22:56:50

FDA-CBER-2022-1614-2945082

US3672203
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:23:55
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
User entered '23 Sep 2020 12:00'	System	18 Sep 2020 17:41:32

FDA-CBER-2022-1614-2945083

US3672203
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:23:55
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
User entered '24 Sep 2020 11:59'	System	18 Sep 2020 17:41:32

FDA-CBER-2022-1614-2945084

US3672203
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:23:55
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
Data entry locked.	System	18 Sep 2020 17:41:32
User entered 'Day 7'	System	18 Sep 2020 17:41:32

US3672203
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:23:55
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-24T21:57:50', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '56898388-6480-4dc5-baa1-0fa2d2d4aba1'	System	25 Sep 2020 01:58:03
User entered 'None (0)'	System	25 Sep 2020 01:58:03

FDA-CBER-2022-1614-2945086

US3672203
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:23:55
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-24T21:57:51', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '56898388-6480-4dc5-baa1-0fa2d2d4aba1'	System	25 Sep 2020 01:58:03
User entered 'None (0)'	System	25 Sep 2020 01:58:03

FDA-CBER-2022-1614-2945087

US3672203
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:23:55
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-24T21:57:52', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '56898388-6480-4dc5-baa1-0fa2d2d4aba1'	System	25 Sep 2020 01:58:03
User entered 'None (0)'	System	25 Sep 2020 01:58:03

FDA-CBER-2022-1614-2945088

US3672203
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:23:55
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-24T21:57:53', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '56898388-6480-4dc5-baa1-0fa2d2d4aba1'	System	25 Sep 2020 01:58:03
User entered 'None (0)'	System	25 Sep 2020 01:58:03

FDA-CBER-2022-1614-2945089

US3672203
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:23:55
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-24T21:57:54', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '56898388-6480-4dc5-baa1-0fa2d2d4aba1'	System	25 Sep 2020 01:58:03
User entered 'None (0)'	System	25 Sep 2020 01:58:03

FDA-CBER-2022-1614-2945090

US3672203
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:23:55
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-24T21:57:55', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '56898388-6480-4dc5-baa1-0fa2d2d4aba1'	System	25 Sep 2020 01:58:03
User entered 'None (0)'	System	25 Sep 2020 01:58:03

FDA-CBER-2022-1614-2945091

US3672203
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:23:55
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 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-24T21:57:57', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '56898388-6480-4dc5-baa1-0fa2d2d4aba1'	System	25 Sep 2020 01:58:03
User entered 'No (N)'	System	25 Sep 2020 01:58:03

FDA-CBER-2022-1614-2945092

US3672203
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:23:55
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-09-24T21:57:59', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '56898388-6480-4dc5-baa1-0fa2d2d4aba1'	System	25 Sep 2020 01:58:03
User entered '24 Sep 2020 21:57'	System	25 Sep 2020 01:58:03

FDA-CBER-2022-1614-2945093

US3672203
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:23:55
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
User entered '24 Sep 2020 12:00'	System	18 Sep 2020 17:41:32

FDA-CBER-2022-1614-2945094

US3672203
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:23:55
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
User entered '25 Sep 2020 11:59'	System	18 Sep 2020 17:41:32

FDA-CBER-2022-1614-2945095

US3672203
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:23:55
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:05:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Sep 2020 19:24:46

FDA-CBER-2022-1614-2945096

US3672203
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:23:55
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:05:51
User entered '28 Sep 2020'	(b) (4), (b) (6)	30 Sep 2020 19:24:46

US3672203
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:23:55
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:05:51
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	30 Sep 2020 19:24:46

FDA-CBER-2022-1614-2945098

US3672203
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:23:55
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:05:51
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 19:24:46

US3672203
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:23:55
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 20:06:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Sep 2020 19:26:03

US3672203
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:23:55
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User entered '1'	System	30 Sep 2020 19:26:03

FDA-CBER-2022-1614-2945101

US3672203
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:23:55
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	19 Oct 2020 17:02:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Oct 2020 20:32:33

US3672203
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:23:55
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	19 Oct 2020 17:02:17
User entered '5 Oct 2020'	(b) (4), (b) (6)	05 Oct 2020 20:32:33

US3672203
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:23:55
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	19 Oct 2020 17:02:17
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	05 Oct 2020 20:32:33

US3672203
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:23:55
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	19 Oct 2020 17:02:17
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 20:32:33

US3672203
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:23:55
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	19 Oct 2020 17:02:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Oct 2020 20:32:36

US3672203
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:23:55
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User entered '1'	System	05 Oct 2020 20:32:36

US3672203
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:23:55
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	19 Oct 2020 17:03:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 21:01:39

US3672203
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:23:55
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	19 Oct 2020 17:03:49
User entered '12 Oct 2020'	(b) (4), (b) (6)	12 Oct 2020 21:01:39

US3672203
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:23:55
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	19 Oct 2020 17:03:49
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	12 Oct 2020 21:01:39

US3672203
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:23:55
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	19 Oct 2020 17:03:49
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 21:01:39

FDA-CBER-2022-1614-2945111

US3672203
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:23:55
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:07
DataPoint Verified.	(b) (4), (b) (6)	19 Oct 2020 17:03:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 21:01:43

US3672203
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:23:55
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User entered '1'	System	12 Oct 2020 21:01:43

US3672203
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:23:55
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:11
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:21:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 21:08:14

FDA-CBER-2022-1614-2945114

US3672203
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:23:55
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:11
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:21:30
User entered '20 Oct 2020'	(b) (4), (b) (6)	20 Oct 2020 21:08:14

FDA-CBER-2022-1614-2945115

US3672203
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:23:55
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 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:11
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:21:30
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	20 Oct 2020 21:08:14

US3672203
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:23:55
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User entered 'VISIT3'	System	20 Oct 2020 21:08:14

FDA-CBER-2022-1614-2945117

US3672203
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:23:55
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:11
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:22:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 21:08:41

FDA-CBER-2022-1614-2945118

US3672203
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:23:55
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:11
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:22:06
User entered '20 Oct 2020'	(b) (4), (b) (6)	20 Oct 2020 21:08:41

FDA-CBER-2022-1614-2945119

US3672203
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:23:55
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:11
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:22:06
User entered '16:55'	(b) (4), (b) (6)	20 Oct 2020 21:08:41

US3672203
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:23:55
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User entered '20 Oct 2020 16:55'	System	20 Oct 2020 21:08:41

US3672203
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:23:55
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:11
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:22:06
User entered '98.6' F	(b) (4), (b) (6)	20 Oct 2020 21:08:41

US3672203
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:23:55
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:11
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:22:06
User entered 'Oral (Oral)'	(b) (4), (b) (6)	20 Oct 2020 21:08:41

US3672203
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:23:55
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:11
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:22:06
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 21:08:41

US3672203
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:23:55
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:11
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:22:06
User entered '71'	(b) (4), (b) (6)	20 Oct 2020 21:08:41

FDA-CBER-2022-1614-2945125

US3672203
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:23:55
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User entered 'bpm'	System	20 Oct 2020 21:08:41

FDA-CBER-2022-1614-2945126

US3672203
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:23:55
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:11
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:22:06
User entered '12'	(b) (4), (b) (6)	20 Oct 2020 21:08:41

FDA-CBER-2022-1614-2945127

US3672203
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:23:55
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User entered 'breaths/min'	System	20 Oct 2020 21:08:41

FDA-CBER-2022-1614-2945128

US3672203
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:23:55
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:11
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:22:06
User entered '125'	(b) (4), (b) (6)	20 Oct 2020 21:08:41

FDA-CBER-2022-1614-2945129

US3672203
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:23:55
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User entered 'mmHg'	System	20 Oct 2020 21:08:41

FDA-CBER-2022-1614-2945130

US3672203
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:23:55
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:11
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:22:06
User entered '90'	(b) (4), (b) (6)	20 Oct 2020 21:08:41

FDA-CBER-2022-1614-2945131

US3672203
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:23:55
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User entered 'mmHg'	System	20 Oct 2020 21:08:41

FDA-CBER-2022-1614-2945132

US3672203
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:23:55
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18

FDA-CBER-2022-1614-2945133

US3672203
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:23:55
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18

FDA-CBER-2022-1614-2945134

US3672203
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Generated On: 10 Jun 2021 09:23:55
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:11
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:22:15
User entered 'No (N)'	(b) (4), (b) (6)	20 Oct 2020 21:08:44

US3672203
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Generated On: 10 Jun 2021 09:23:55
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:11
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:22:15
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 21:08:44

FDA-CBER-2022-1614-2945136

US3672203
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:23:55
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:11
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:22:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 21:08:53

US3672203
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:23:55
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:11
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:22:31
User entered '20 Oct 2020'	(b) (4), (b) (6)	20 Oct 2020 21:08:53

US3672203
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:23:55
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:11
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:22:31
User entered '17:00'	(b) (4), (b) (6)	20 Oct 2020 21:08:53

US3672203
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:23:55
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User entered '20 Oct 2020 17:00'	System	20 Oct 2020 21:08:53

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US3672203
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:23:55
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	15 Feb 2021 20:03:11
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:22:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 21:09:03

US3672203
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:23:55
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User entered '1'	System	20 Oct 2020 21:09:03

US3672203
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:23:55
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
Data entry locked.	System	19 Aug 2020 20:49:04
User entered 'Day 64'	System	19 Aug 2020 20:49:04

US3672203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:55

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 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-10-21T12:06:48', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: 'a0ca77e2-6951-46a6-88b1-4807ff77965f'	System	21 Oct 2020 16:07:00
User entered 'No (N)'	System	21 Oct 2020 16:07:00

US3672203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:55

Have you been exposed to someone with 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 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-10-21T12:06:55', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: 'a0ca77e2-6951-46a6-88b1-4807ff77965f'	System	21 Oct 2020 16:07:00
User entered 'No (N)'	System	21 Oct 2020 16:07:00

US3672203
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:23:55
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-10-21T12:06:58', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: 'a0ca77e2-6951-46a6-88b1-4807ff77965f'	System	21 Oct 2020 16:07:00
User entered '21 Oct 2020 12:06:58'	System	21 Oct 2020 16:07:00

US3672203
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:23:55
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
Data entry locked.	System	19 Aug 2020 20:49:04
User entered '19 Oct 2020 00:01'	System	19 Aug 2020 20:49:04

US3672203
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:23:55
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
Data entry locked.	System	19 Aug 2020 20:49:04
User entered '23 Oct 2020 23:59'	System	19 Aug 2020 20:49:04

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US3672203
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:23:55
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
Data entry locked.	System	19 Aug 2020 20:49:04
User entered 'Day 71'	System	19 Aug 2020 20:49:04

US3672203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:55

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 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-10-29T18:00:58', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '17231c54-6946-4995-826d-654aaebe9a94'	System	29 Oct 2020 22:01:09
User entered 'No (N)'	System	29 Oct 2020 22:01:09

US3672203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:55

Have you been exposed to someone with 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 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-10-29T18:01:02', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '17231c54-6946-4995-826d-654aaebe9a94'	System	29 Oct 2020 22:01:09
User entered 'No (N)'	System	29 Oct 2020 22:01:09

US3672203
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:23:55
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-10-29T18:01:05', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '17231c54-6946-4995-826d-654aaebe9a94'	System	29 Oct 2020 22:01:09
User entered '29 Oct 2020 18:01:05'	System	29 Oct 2020 22:01:09

US3672203
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:23:55
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
Data entry locked.	System	19 Aug 2020 20:49:04
User entered '26 Oct 2020 00:01'	System	19 Aug 2020 20:49:04

US3672203
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:23:55
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
Data entry locked.	System	19 Aug 2020 20:49:04
User entered '30 Oct 2020 23:59'	System	19 Aug 2020 20:49:04

FDA-CBER-2022-1614-2945154

US3672203
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:23:55
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
Data entry locked.	System	19 Aug 2020 20:49:04
User entered 'Day 78'	System	19 Aug 2020 20:49:04

US3672203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:55

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 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-11-06T11:59:18', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: 'e19b7092-77bb-497e-8721-2b07f2b16927'	System	06 Nov 2020 16:59:34
User entered 'No (N)'	System	06 Nov 2020 16:59:34

US3672203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:55

Have you been exposed to someone with 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 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-11-06T11:59:21', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: 'e19b7092-77bb-497e-8721-2b07f2b16927'	System	06 Nov 2020 16:59:34
User entered 'No (N)'	System	06 Nov 2020 16:59:34

US3672203
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:23:55
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-11-06T11:59:24', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: 'e19b7092-77bb-497e-8721-2b07f2b16927'	System	06 Nov 2020 16:59:34
User entered '06 Nov 2020 11:59:24'	System	06 Nov 2020 16:59:34

FDA-CBER-2022-1614-2945158

US3672203
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:23:55
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
Data entry locked.	System	19 Aug 2020 20:49:04
User entered '02 Nov 2020 00:01'	System	19 Aug 2020 20:49:04

US3672203
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:23:55
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
Data entry locked.	System	19 Aug 2020 20:49:04
User entered '06 Nov 2020 23:59'	System	19 Aug 2020 20:49:04

US3672203
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:23:55
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
Data entry locked.	System	19 Aug 2020 20:49:04
User entered 'Day 92'	System	19 Aug 2020 20:49:04

US3672203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:55

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 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-11-16T00:01:51', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '521c91ab-c41e-4e39-a724-d8ade1320150'	System	16 Nov 2020 05:02:05
User entered 'No (N)'	System	16 Nov 2020 05:02:05

US3672203

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:55

Have you been exposed to someone with 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 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-11-16T00:01:55', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '521c91ab-c41e-4e39-a724-d8ade1320150'	System	16 Nov 2020 05:02:05
User entered 'No (N)'	System	16 Nov 2020 05:02:05

US3672203
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:23:55
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-11-16T00:01:58', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '521c91ab-c41e-4e39-a724-d8ade1320150'	System	16 Nov 2020 05:02:05
User entered '16 Nov 2020 00:01:58'	System	16 Nov 2020 05:02:05

US3672203
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:23:55
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
Data entry locked.	System	19 Aug 2020 20:49:04
User entered '16 Nov 2020 00:01'	System	19 Aug 2020 20:49:04

US3672203
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:23:55
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:27:22
Data entry locked.	System	19 Aug 2020 20:49:04
User entered '20 Nov 2020 23:59'	System	19 Aug 2020 20:49:04

US3672203
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:23:55
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:24
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 23:17:24

US3672203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:55

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 21:13:18

US3672203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:55

Have you been exposed to someone with 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 21:13:18

US3672203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:55

Please 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 21:13:18

US3672203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:55

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 21:13:18

US3672203
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:23:55
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18

US3672203
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:23:55
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18

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US3672203
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:23:55
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18

FDA-CBER-2022-1614-2945174

US3672203
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:23:55
Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18

FDA-CBER-2022-1614-2945175

US3672203
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:23:55
Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18

FDA-CBER-2022-1614-2945176

US3672203
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:23:55
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18

US3672203
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:23:55
Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18

FDA-CBER-2022-1614-2945178

US3672203
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:23:55
Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18

FDA-CBER-2022-1614-2945179

US3672203
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:23:55
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18

FDA-CBER-2022-1614-2945180

US3672203
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:23:55
New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18

US3672203
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:23:55
New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18

US3672203
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:23:55
Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18

FDA-CBER-2022-1614-2945183

US3672203
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:23:55
Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18

US3672203
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:23:55
Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18

US3672203
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:23:55
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18

FDA-CBER-2022-1614-2945186

US3672203
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:23:55
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18

FDA-CBER-2022-1614-2945187

US3672203
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:23:55
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18

FDA-CBER-2022-1614-2945188

US3672203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:55

Please 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 21:13:18

US3672203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:55

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 21:13:18

US3672203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:55

Please 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 21:13:18

US3672203
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:23:55
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18

US3672203
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:23:55
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:24
Amendment Manager: User entered '20 Nov 2020 00:01'	System	19 Nov 2020 23:17:24

US3672203
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:23:55
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:24
Amendment Manager: User entered '24 Nov 2020 23:59'	System	19 Nov 2020 23:17:24

FDA-CBER-2022-1614-2945194

US3672203
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:23:55
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:24
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 23:17:24

US3672203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:55

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 21:13:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-11-27T00:02:00', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '87d7774d-93c8-4a36-87c7-9928ef615342'	System	27 Nov 2020 05:02:18
User entered 'No (N)'	System	27 Nov 2020 05:02:18

US3672203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:55

Have you been exposed to someone with 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 21:13:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-11-27T00:02:03', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '87d7774d-93c8-4a36-87c7-9928ef615342'	System	27 Nov 2020 05:02:18
User entered 'No (N)'	System	27 Nov 2020 05:02:18

US3672203
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:23:55
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-11-27T00:02:05', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '87d7774d-93c8-4a36-87c7-9928ef615342'	System	27 Nov 2020 05:02:18
User entered '27 Nov 2020 00:02:05'	System	27 Nov 2020 05:02:18

FDA-CBER-2022-1614-2945198

US3672203
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:23:55
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:24
Amendment Manager: User entered '27 Nov 2020 00:01'	System	19 Nov 2020 23:17:24

US3672203
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:23:55
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:24
Amendment Manager: User entered '01 Dec 2020 23:59'	System	19 Nov 2020 23:17:24

US3672203
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:23:55
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:24
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 23:17:24

US3672203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:55

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 21:13:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-12-04T00:01:20', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '72377ce2-ecd5-4fe6-94bb-b2cae656d396'	System	04 Dec 2020 05:01:42
User entered 'Yes (Y)'	System	04 Dec 2020 05:01:42

US3672203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:55

Have you been exposed to someone with 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 21:13:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-12-04T00:01:23', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '72377ce2-ecd5-4fe6-94bb-b2cae656d396'	System	04 Dec 2020 05:01:42
User entered 'No (N)'	System	04 Dec 2020 05:01:42

US3672203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:55

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 21:13:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-12-04T00:01:26', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '72377ce2-ecd5-4fe6-94bb-b2cae656d396'	System	04 Dec 2020 05:01:42
User entered 'No (N)'	System	04 Dec 2020 05:01:42

US3672203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:55

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 21:13:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-12-04T00:01:29', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '72377ce2-ecd5-4fe6-94bb-b2cae656d396'	System	04 Dec 2020 05:01:42
User entered 'No (N)'	System	04 Dec 2020 05:01:42

US3672203
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:23:55
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-12-04T00:01:31', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '72377ce2-ecd5-4fe6-94bb-b2cae656d396'	System	04 Dec 2020 05:01:42
User entered '04 Dec 2020 00:01:31'	System	04 Dec 2020 05:01:42

FDA-CBER-2022-1614-2945206

US3672203
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:23:55
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:24
Amendment Manager: User entered '04 Dec 2020 00:01'	System	19 Nov 2020 23:17:24

FDA-CBER-2022-1614-2945207

US3672203
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:23:55
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:24
Amendment Manager: User entered '08 Dec 2020 23:59'	System	19 Nov 2020 23:17:24

US3672203
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:23:55
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:24
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 23:17:24

US3672203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:55

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 21:13:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-12-11T00:01:28', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '4e807e60-4ffc-40ba-a6e4-f4eec66e20da'	System	11 Dec 2020 05:02:36
User entered 'No (N)'	System	11 Dec 2020 05:02:36

US3672203

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:23:55

Have you been exposed to someone with 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 21:13:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-12-11T00:01:31', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '4e807e60-4ffc-40ba-a6e4-f4eec66e20da'	System	11 Dec 2020 05:02:36
User entered 'No (N)'	System	11 Dec 2020 05:02:36

US3672203
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:23:55
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4458A69D-239C-491C-9D34-B799439BC875)', Time: '2020-12-11T00:01:33', User OID: 'PatientReportedOutcome (US3672203)', ODM File OID: '4e807e60-4ffc-40ba-a6e4-f4eec66e20da'	System	11 Dec 2020 05:02:36
User entered '11 Dec 2020 00:01:33'	System	11 Dec 2020 05:02:36

US3672203
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:23:55
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:24
Amendment Manager: User entered '11 Dec 2020 00:01'	System	19 Nov 2020 23:17:24

US3672203
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:23:55
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:17:24
Amendment Manager: User entered '15 Dec 2020 23:59'	System	19 Nov 2020 23:17:24

US3672203
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:23:55
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:41:49
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 15:55:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Nov 2020 20:23:35

US3672203
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:23:55
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:41:49
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 15:55:36
User entered '14 Nov 2020'	(b) (4), (b) (6)	14 Nov 2020 20:23:35

US3672203
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:23:55
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:49
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 15:55:36
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	14 Nov 2020 20:23:35

FDA-CBER-2022-1614-2945217

US3672203
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:23:55
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:41:49
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 15:55:36
User entered empty.	(b) (4), (b) (6)	14 Nov 2020 20:23:35

US3672203
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:23:55
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:41:49
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 15:55:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Nov 2020 20:23:38

US3672203
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:23:55
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User entered '1'	System	14 Nov 2020 20:23:38

FDA-CBER-2022-1614-2945220

US3672203
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:23:55
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:41:49
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 13:57:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Dec 2020 18:07:25

US3672203
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:23:55
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:41:49
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 13:57:31
User entered '11 Dec 2020'	(b) (4), (b) (6)	11 Dec 2020 18:07:25

US3672203
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:23:55
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:49
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 13:57:31
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	11 Dec 2020 18:07:25

US3672203
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:23:55
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:41:49
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 13:57:31
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 18:07:25

FDA-CBER-2022-1614-2945224

US3672203
Folder: Safety Call Day 119 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:23:55
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:41:49
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 13:57:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Dec 2020 18:07:30

US3672203
Folder: Safety Call Day 119 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:23:55
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User entered '1'	System	11 Dec 2020 18:07:30

US3672203
Folder: Adverse Events
Form: Adverse Events Summary
Generated On: 10 Jun 2021 09:23:55
Did the participant experience any adverse events?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:41:49
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 13:58:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Jan 2021 14:10:32

US3672203
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:23:55
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:41:49
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 13:59:35
User entered 'USA-US116-2021-mRNA-1273-P301000003'	System	21 Jan 2021 18:22:19
User entered 'New'	(b) (4), (b) (6)	21 Jan 2021 18:22:19

US3672203
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:23:55
Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:41:49
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 13:59:35
User coded data point as SOC: Psychiatric disorders, HLGT: Suicidal and self-injurious behaviours NEC, HLT: Suicidal and self-injurious behaviour, PT: Completed suicide, LLT: Completed suicide - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Jan 2021 00:13:11
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Jan 2021 00:13:11
Data point term sent to Coder	System	20 Jan 2021 19:47:06
User entered 'Committed suicide'	(b) (4), (b) (6)	20 Jan 2021 19:46:18

US3672203
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:23:55
Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:41:49
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 13:59:35
User entered 'No (N)'	(b) (4), (b) (6)	20 Jan 2021 19:46:18

FDA-CBER-2022-1614-2945230

US3672203
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:23:55
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:41:49
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 13:59:35
User entered 'No (N)'	(b) (4), (b) (6)	20 Jan 2021 19:46:18

FDA-CBER-2022-1614-2945231

US3672203
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:23:55
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:41:49
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 13:59:35
User entered 'No (N)'	(b) (4), (b) (6)	20 Jan 2021 19:46:18

US3672203
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:23:55
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:41:49
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 13:59:35
User entered '13 Dec 2020'	(b) (4), (b) (6)	20 Jan 2021 19:46:18

US3672203
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:23:55
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:41:49
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 13:59:35
User entered empty.	(b) (4), (b) (6)	20 Jan 2021 19:46:18

US3672203
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:23:55
AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User entered empty.	System	20 Jan 2021 19:46:18

US3672203
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:23:55
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:41:49
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 13:59:35
User entered 'No (N)'	(b) (4), (b) (6)	20 Jan 2021 19:46:18

US3672203
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:23:55
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:41:49
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 13:59:35
User closed query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	20 Jan 2021 19:46:45
User entered '13 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Jan 2021 19:46:45
User opened query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	20 Jan 2021 19:46:18
User entered empty.	(b) (4), (b) (6)	20 Jan 2021 19:46:18

US3672203
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:23:55
End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:41:49
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 13:59:35
User entered empty.	(b) (4), (b) (6)	20 Jan 2021 19:46:18

US3672203
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:23:55
AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User entered empty.	System	20 Jan 2021 19:46:18

US3672203
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:23:55
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:41:49
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 13:59:35
User entered 'Grade 4 (Grade 4)'	(b) (4), (b) (6)	20 Jan 2021 19:46:18

US3672203
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:23:55
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:41:49
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 13:59:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Jan 2021 19:46:18

US3672203
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:23:55
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:41:49
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 13:59:35
User entered '1'	(b) (4), (b) (6)	20 Jan 2021 19:46:18

US3672203
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:23:55
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:41:49
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 13:59:35
User entered '0'	(b) (4), (b) (6)	20 Jan 2021 19:46:18

US3672203
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:23:55
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:41:49
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 13:59:35
User entered '0'	(b) (4), (b) (6)	20 Jan 2021 19:46:18

US3672203
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:23:55
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:41:49
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 13:59:35
User entered empty.	(b) (4), (b) (6)	20 Jan 2021 19:46:18

US3672203
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:23:55
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:41:49
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 13:59:35
User entered empty.	(b) (4), (b) (6)	20 Jan 2021 19:46:18

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US3672203
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:23:55
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:41:49
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 13:59:35
User entered empty.	(b) (4), (b) (6)	20 Jan 2021 19:46:18

US3672203
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:23:55
Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:41:49
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 13:59:35
User entered empty.	(b) (4), (b) (6)	20 Jan 2021 19:46:18

US3672203
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:23:55
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:41:49
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 13:59:35
User entered '0'	(b) (4), (b) (6)	20 Jan 2021 19:46:18

US3672203
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:23:55
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:41:49
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 13:59:35
User entered '0'	(b) (4), (b) (6)	20 Jan 2021 19:46:18

US3672203
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:23:55
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:41:49
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 13:59:35
User entered '0'	(b) (4), (b) (6)	20 Jan 2021 19:46:18

US3672203
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:23:55
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:41:49
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 13:59:35
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	20 Jan 2021 19:46:18

US3672203
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:23:55
Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:41:49
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 13:59:35
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	20 Jan 2021 19:46:18

US3672203
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:23:55
Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:49
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 13:59:35
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	20 Jan 2021 19:46:18

US3672203
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:23:55
None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:41:49
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 13:59:35
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	20 Jan 2021 20:05:52
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Jan 2021 20:05:52
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	20 Jan 2021 19:46:18
User entered '0'	(b) (4), (b) (6)	20 Jan 2021 19:46:18

US3672203
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:23:55
Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:41:49
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 13:59:35
User entered '0'	(b) (4), (b) (6)	20 Jan 2021 19:46:18

US3672203
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:23:55
Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:41:49
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 13:59:35
User entered '0'	(b) (4), (b) (6)	20 Jan 2021 19:46:18

US3672203
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:23:55
Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:41:49
User closed query 'Per CDM: Outcome=Fatal, so please complete the details in "End of study" form.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 03:22:15
Query 'Per CDM: Outcome=Fatal, so please complete the details in "End of study" form.' answered with 'completed' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 22:38:18
User opened query 'Per CDM: Outcome=Fatal, so please complete the details in "End of study" form.' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 08:02:31
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 13:59:35
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Jan 2021 20:05:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Jan 2021 20:05:52
User entered 'Fatal (FATAL)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Jan 2021 20:05:52
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Jan 2021 19:46:18
User entered empty.	(b) (4), (b) (6)	20 Jan 2021 19:46:18

US3672203
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:23:55
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 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:41:49
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 13:59:35
User entered empty.	(b) (4), (b) (6)	20 Jan 2021 19:46:18

US3672203
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:23:55
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:41:49
User closed query 'PV Query: Please provide autopsy results if performed. If not performed, please state so.' (Site from Safety).	(b) (4), (b) (6)	05 Feb 2021 17:53:27
User closed query 'PV Query: Please query for relevant details surrounding suicide such as any emotional or psychological issues leading to the event' (Site from Safety).	(b) (4), (b) (6)	05 Feb 2021 17:53:25
Query 'PV Query: Please provide autopsy results if performed. If not performed, please state so.' answered with 'not performed' (Site from Safety).	(b) (4), (b) (6)	04 Feb 2021 20:43:02
Query 'PV Query: Please query for relevant details surrounding suicide such as any emotional or psychological issues leading to the event' answered with 'only relevant med hx anxiety already listed' (Site from Safety).	(b) (4), (b) (6)	04 Feb 2021 20:42:49
User opened query 'PV Query: Please provide autopsy results if performed. If not performed, please state so.' (Site from Safety).	(b) (4), (b) (6)	29 Jan 2021 16:13:24
User opened query 'PV Query: Please query for relevant details surrounding suicide such as any emotional or psychological issues leading to the event' (Site from Safety).	(b) (4), (b) (6)	29 Jan 2021 16:13:17
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 13:59:35
User entered 'Site staff spoke to subject's mother regarding participation in study and she had informed us that her son had committed suicide on 12/13/2020.' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Jan 2021 19:47:54
User entered 'Spoke to Subject's mother and she had stated he committed suicide on 12/13/2020.'	(b) (4), (b) (6)	20 Jan 2021 19:46:18

US3672203
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:23:55
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User entered '1'	System	20 Jan 2021 19:46:18

US3672203
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:23:55
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User entered '0'	System	20 Jan 2021 19:46:18

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US3672203
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:23:55
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18

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US3672203
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination Summary
Generated On: 10 Jun 2021 09:23:55
Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:41:49
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:46:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 21:04:01

US3672203
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:23:55
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:41:49
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:46:51
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: ESCITALOPRAM OXALATE, PRODUCTSYNONYM: LEXAPRO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 21:06:14
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 21:06:14
Data point term sent to Coder	System	19 Aug 2020 21:05:43
User entered 'lexapro'	(b) (4), (b) (6)	19 Aug 2020 21:04:54

US3672203
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:23:55
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:41:49
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:46:51
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 21:04:54

US3672203
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:23:55
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:41:49
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:46:51
User entered 'anxiety'	(b) (4), (b) (6)	19 Aug 2020 21:04:54

US3672203
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:23:55
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:41:49
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:46:51
User entered '10'	(b) (4), (b) (6)	19 Aug 2020 21:04:54

US3672203
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:23:55
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:41:49
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:46:51
User entered 'mg (mg)'	(b) (4), (b) (6)	19 Aug 2020 21:04:54

US3672203
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:23:55
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:41:49
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:46:51
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 21:04:54

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US3672203
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:23:55
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:41:49
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:46:51
User entered 'once daily (QD)'	(b) (4), (b) (6)	19 Aug 2020 21:04:54

US3672203
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:23:55
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:41:49
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:46:51
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 21:04:54

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US3672203
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:23:55
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:41:49
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:46:51
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	19 Aug 2020 21:04:54

US3672203
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:23:55
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:49
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:46:51
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 21:04:54

US3672203
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:23:55
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:49
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:46:51
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.' canceled (Site from System).	(b) (4), (b) (6)	20 Aug 2020 18:45:14
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	19 Aug 2020 21:04:54
User entered 'un Jan 2020'	(b) (4), (b) (6)	19 Aug 2020 21:04:54

US3672203
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:23:55
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:41:49
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:46:51
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 21:04:54

US3672203
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:23:55
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:41:49
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:46:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 21:04:54

US3672203
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:23:55
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:41:49
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:46:51
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 21:04:54

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US3672203
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:23:55
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:41:49
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 18:46:51
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 21:04:54

FDA-CBER-2022-1614-2945279

US3672203
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:23:55
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User entered '1'	System	19 Aug 2020 21:04:54

US3672203
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:23:55
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User entered '1'	System	19 Aug 2020 21:04:54

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US3672203
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:23:55
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User entered '804 (804)'	System	19 Aug 2020 21:04:54

FDA-CBER-2022-1614-2945282

US3672203
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures Summary
Generated On: 10 Jun 2021 09:23:55
Were any concomitant procedures performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:41:49
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 14:00:17
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 21:01:19

FDA-CBER-2022-1614-2945283

US3672203
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 10 Jun 2021 09:23:55
Date of study discontinuation/completion *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:17:54
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:49
User entered '13 Dec 2020'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 22:37:56

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US3672203
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 10 Jun 2021 09:23:55
Reason for discontinuation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:17:54
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:49
User entered 'Death (DEATH)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 22:37:56

FDA-CBER-2022-1614-2945285

US3672203
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 10 Jun 2021 09:23:55
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 21:13:18
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:17:54
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:49
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 22:37:56

US3672203
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 10 Jun 2021 09:23:55
If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User closed query 'Per CDM: "Suicide" is entered as an Adverse Event therefore the cause of death should be captured as Adverse Event on the study discontinuation form. Please reconcile.' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 18:32:23
User signature succeeded.	Cynthia Strout (b) (4)	20 Apr 2021 15:32:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:17:54
Query 'Per CDM: "Suicide" is entered as an Adverse Event therefore the cause of death should be captured as Adverse Event on the study discontinuation form. Please reconcile.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 16:56:44
Signature has been broken.	(b) (4), (b) (6)	19 Apr 2021 16:56:26
User entered 'Adverse event (ADVERSE EVENT)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Apr 2021 16:56:26
User opened query 'Per CDM: "Suicide" is entered as an Adverse Event therefore the cause of death should be captured as Adverse Event on the study discontinuation form. Please reconcile.' (Site from DM).	(b) (4), (b) (6)	17 Apr 2021 16:32:04
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:49
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 22:37:56

US3672203
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 10 Jun 2021 09:23:55
If main cause of death is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4)	20 Apr 2021 15:32:48
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:17:54
Signature has been broken.	(b) (4), (b) (6)	19 Apr 2021 16:56:26
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	19 Apr 2021 16:56:26
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:49
User entered 'Committed suicide'	(b) (4), (b) (6)	18 Feb 2021 22:37:56

US3672203
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 10 Jun 2021 09:23:55
Date of death *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:17:54
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:49
User entered '13 Dec 2020'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 22:37:56

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US3672203
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 10 Jun 2021 09:23:55
Was autopsy performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:17:54
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:49
User entered 'Unknown (UNK)'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 22:37:56

FDA-CBER-2022-1614-2945290

US3672203
Folder: SAE USA-US116-2021-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:23:55
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:41:49
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 13:59:55
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 18:22:42
User entered 'USA-US116-2021-MRNA-1273-P301000003'	System	21 Jan 2021 18:22:19

US3672203
Folder: SAE USA-US116-2021-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:23:55
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:41:49
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 13:59:55
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 18:22:42
User entered 'Yes (Y)'	System	21 Jan 2021 18:22:19

US3672203
Folder: SAE USA-US116-2021-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:23:55
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:41:49
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 13:59:55
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 18:22:42
User entered 'Yes (Y)'	System	21 Jan 2021 18:22:19

US3672203
Folder: SAE USA-US116-2021-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:23:55
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:41:49
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 13:59:55
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 18:22:42
User entered 'No (N)'	System	21 Jan 2021 18:22:19

US3672203
Folder: SAE USA-US116-2021-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:23:55
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:41:49
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 13:59:55
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 18:22:42
User entered 'No (N)'	System	21 Jan 2021 18:22:19

US3672203
Folder: SAE USA-US116-2021-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:23:55
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:41:49
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 13:59:55
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 18:22:42
User entered 'No (N)'	System	21 Jan 2021 18:22:19

US3672203
Folder: SAE USA-US116-2021-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:23:55
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:41:49
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 13:59:55
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 18:22:42
User entered 'No (N)'	System	21 Jan 2021 18:22:19

US3672203
Folder: SAE USA-US116-2021-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:23:55
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:41:49
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 13:59:55
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 18:22:42
User entered 'No (N)'	System	21 Jan 2021 18:22:19

US3672203
Folder: SAE USA-US116-2021-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:23:55
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:41:49
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 13:59:55
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 18:22:42
User entered 'Cynthia'	System	21 Jan 2021 18:22:19

US3672203
Folder: SAE USA-US116-2021-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:23:55
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:41:49
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 13:59:55
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 18:22:42
User entered 'Strout'	System	21 Jan 2021 18:22:19

US3672203
Folder: SAE USA-US116-2021-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:23:55
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:41:49
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 13:59:55
Un-reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 19:41:36
User entered '4920 O HEAR AVE SUITE 101' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 19:41:36
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 18:22:42
User entered '1156 Bowman Road'	System	21 Jan 2021 18:22:19

US3672203
Folder: SAE USA-US116-2021-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:23:55
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:41:49
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 13:59:55
Un-reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 19:41:36
User entered 'North Charleston' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 19:41:36
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 18:22:42
User entered 'Mount Pleasant'	System	21 Jan 2021 18:22:19

US3672203
Folder: SAE USA-US116-2021-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:23:55
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:41:49
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 13:59:55
User entered 'sc'	(b) (4), (b) (6)	21 Jan 2021 18:55:07

FDA-CBER-2022-1614-2945303

US3672203
Folder: SAE USA-US116-2021-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:23:55
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:49
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 13:59:55
Un-reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 19:41:36
User entered '29405' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 19:41:36
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 18:22:42
User entered '29464'	System	21 Jan 2021 18:22:19

US3672203
Folder: SAE USA-US116-2021-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:23:55
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:41:49
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 13:59:55
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 18:22:42
User entered 'US'	System	21 Jan 2021 18:22:36

US3672203
Folder: SAE USA-US116-2021-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:23:55
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User entered '1'	System	21 Jan 2021 18:22:36

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US3672203
Folder: SAE USA-US116-2021-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:23:55
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:41:49
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 13:59:55
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 18:22:42
User entered 'USA-US116-2021-MRNA-1273-P301000003'	System	21 Jan 2021 18:22:19

US3672203
Folder: SAE USA-US116-2021-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:23:55
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:41:49
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 13:59:55
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 18:22:42
User entered 'Yes (Y)'	System	21 Jan 2021 18:22:19

US3672203
Folder: SAE USA-US116-2021-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:23:55
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:41:49
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 13:59:55
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 18:22:42
User entered 'Yes (Y)'	System	21 Jan 2021 18:22:19

US3672203
Folder: SAE USA-US116-2021-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:23:55
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:41:49
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 13:59:55
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 18:22:42
User entered 'No (N)'	System	21 Jan 2021 18:22:19

US3672203
Folder: SAE USA-US116-2021-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:23:55
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:49
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 13:59:55
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 18:22:42
User entered 'No (N)'	System	21 Jan 2021 18:22:19

US3672203
Folder: SAE USA-US116-2021-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:23:55
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:41:49
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 13:59:55
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 18:22:42
User entered 'No (N)'	System	21 Jan 2021 18:22:19

US3672203
Folder: SAE USA-US116-2021-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:23:55
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:49
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 13:59:55
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 18:22:42
User entered 'No (N)'	System	21 Jan 2021 18:22:19

US3672203
Folder: SAE USA-US116-2021-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:23:55
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:49
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 13:59:55
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 18:22:42
User entered 'No (N)'	System	21 Jan 2021 18:22:19

US3672203
Folder: SAE USA-US116-2021-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:23:55
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:41:49
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 13:59:55
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 18:22:42
User entered 'Cynthia'	System	21 Jan 2021 18:22:19

US3672203
Folder: SAE USA-US116-2021-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:23:55
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:49
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 13:59:55
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 18:22:42
User entered 'Strout'	System	21 Jan 2021 18:22:19

US3672203
Folder: SAE USA-US116-2021-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:23:55
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 17:41:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 13:59:55
Un-reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 19:41:36
User entered '4920 O HEAR AVE SUITE 101' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 19:41:36
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 18:22:42
User entered '1156 Bowman Road'	System	21 Jan 2021 18:22:19

US3672203
Folder: SAE USA-US116-2021-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:23:55
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:41:49
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 13:59:55
Un-reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 19:41:36
User entered 'North Charleston' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 19:41:36
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 18:22:42
User entered 'Mount Pleasant'	System	21 Jan 2021 18:22:19

FDA-CBER-2022-1614-2945318

US3672203
Folder: SAE USA-US116-2021-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:23:55
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:41:49
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 13:59:55
User entered 'sc'	(b) (4), (b) (6)	21 Jan 2021 18:55:07

FDA-CBER-2022-1614-2945319

US3672203
Folder: SAE USA-US116-2021-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:23:55
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:41:49
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 13:59:55
Un-reviewed for Safety.	(b) (4), (b) (6)	22 Jan 2021 19:41:36
User entered '29405' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Jan 2021 19:41:36
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 18:22:42
User entered '29464'	System	21 Jan 2021 18:22:19

US3672203
Folder: SAE USA-US116-2021-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:23:55
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:41:49
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 13:59:55
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 18:22:42
User entered 'US'	System	21 Jan 2021 18:22:36

US3672203
Folder: SAE USA-US116-2021-MRNA-1273-P301000003
Form: Safety Report Form
Generated On: 10 Jun 2021 09:23:55
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User entered '1'	System	21 Jan 2021 18:22:36

US3672203
Folder: SAE USA-US116-2021-MRNA-1273-P301000003
Form: Safety Report Form (1)
Generated On: 10 Jun 2021 09:23:55
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:41:49
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 13:59:55
User entered '21/Jan/2021 13:22'	System	21 Jan 2021 18:22:36

US3672203

Folder: SAE USA-US116-2021-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:23:55

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:13:18
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 17:41:49
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 13:59:55
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 18:22:42
User entered '1'	(b) (4), (b) (6)	21 Jan 2021 18:22:36