US3692001 (Prod: University of North Carolina at Chapel Hill)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:24:06

All time stamps listed in this document are displayed in GMT

US3692001
Form: Participant Creation
Data signed: (b) (4) **19 Feb 2021 23:32:07**
Generated On: 10 Jun 2021 09:24:06

Participant ID	US3692001

mRNA-1273-P301 Completion Guidelines

US3692001

Folder: Screening

Form: Visit Date

Data signed: (b) (4) **01 Apr 2021 21:15:32**

Generated On: 10 Jun 2021 09:24:06

Was this visit performed?	Yes ●
	No ◯

Visit date (dd MMM yyyy)	25 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ●
	Clinic ◯

Folder OID	SCRN

US3692001

Folder: Screening

Form: Demographics

Data signed: (b) (4) **13 Feb 2021 00:45:24**

Generated On: 10 Jun 2021 09:24:06

Date of Birth (MMM yyyy)	(b) (6) 1963
Age	56
Age Units	YEARS
Age (Derived)	56

Sex	
	Female ◯
	Male ⬤

Ethnicity	
	Hispanic or Latino ◯
	Not Hispanic or Latino ⬤
	Not Reported ◯
	Unknown ◯

Race (Check All That Apply)

White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify	
Unknown	False
Not reported	False

Date of Informed Consent *(dd MMM yyyy)*	25 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020

Protocol Version

- Amendment 1 ○
- Amendment 2 ○
- Amendment 3 ●
- Amendment 4 ○
- Amendment 5 ○

Was participant enrolled in the study?

- Yes ●
- No ○

If No, indicate reason for screen fail

- Withdrew Consent ○
- Inclusion/Exclusion ○
- Cohort Full ○
- Other ○

If reason for screen fail is Other, specify _____

Was this participant screened previously?

- Yes ○
- No ●

If Yes, previous participant number _____

Enrollment Trigger	1

FDA-CBER-2022-1614-3321479

US3692001

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4)   **13 Feb 2021 00:45:24**

Generated On: 10 Jun 2021 09:24:06

Did the participant meet all eligibility criteria?   Yes ⬤

No ◯

Folder: Screening
Form: Medical History Summary
Data signed: (b) (4) **13 Feb 2021 00:45:24**
Generated On: 10 Jun 2021 09:24:06

Were any significant conditions reported?   Yes ⬤

No ◯

US3692001

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) **13 Feb 2021 00:45:24**

Generated On: 10 Jun 2021 09:24:06

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

US3692001

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) **13 Feb 2021 00:45:24**

Generated On: 10 Jun 2021 09:24:06

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

US3692001

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) **13 Feb 2021 00:45:24**

Generated On: 10 Jun 2021 09:24:06

Condition	GERD (GASTROESOPHAGEAL REFLUX DISEASE)
Start date (dd MMM yyyy)	UN JAN 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes ⬤
	No ◯
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

US3692001

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) **13 Feb 2021 00:45:24**

Generated On: 10 Jun 2021 09:24:06

Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	26 AUG 2020
Time of assessment *(00:00-23:59)*	12:15 (24 HR)
Vital Signs Date and Time (derived)	26 AUG 2020 12:15
Height *(xxx.x)*	175.2 cm
Weight *(xxx.x)*	75.0 kg
BMI *(xxx.x)*	24.43392 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)	

US3692001

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) **13 Feb 2021 00:45:24**

Generated On: 10 Jun 2021 09:24:06

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.

US3692001

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) **13 Feb 2021 00:45:24**

Generated On: 10 Jun 2021 09:24:06

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

US3692001

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) **13 Feb 2021 00:45:24**

Generated On: 10 Jun 2021 09:24:06

WORKS IN AN OFFICE; 13
OTHERS MOSTLY MASKED.
PATIENT LAWYER - FACE TO
FACE INTERACTION & CLIENTS
1-2 PEOPLE/DAY MIN, NOT
ALWAYS MASKED. FREQUENT
TRAVELING TO
BUSINESSES/FACILITIES. EX
NEXT WEEK BOSTON

Location and Living Circumstances Risk (check all that apply)	
No Risk Identified	False
Resides in Nursing Home or Assisted Living Facility	False
Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	True
Other	False
Specify	

US3692001
Folder: Visit 1 Day 1
Form: Visit Date
Data signed: (b) (4) **13 Feb 2021 00:45:24**
Generated On: 10 Jun 2021 09:24:06

Was this visit performed?	Yes ●
	No ○
Visit date (dd MMM yyyy)	26 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●
Folder OID	VISIT1

US3692001

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) **13 Feb 2021 00:45:24**

Generated On: 10 Jun 2021 09:24:06

What was the date of randomization? *(dd MMM yyyy)*	26 AUG 2020
What was the participant's randomization number?	108791

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 ●

US3692001

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) **13 Feb 2021 00:45:24**

Generated On: 10 Jun 2021 09:24:06

Height	ND - Not Done
Weight	ND - Not Done

US3692001

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) **13 Feb 2021 00:45:24**

Generated On: 10 Jun 2021 09:24:06

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)*	26 AUG 2020
Time of assessment *(00:00-23:59)*	12:15 (24 HR)
Vital Signs Date and Time (derived)	26 AUG 2020 12:15
Temperature *(xxx.x)*	36.8 C
Route of measurement	Oral ●
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	70 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	71 mmHg
Diastolic Blood Pressure units	MMHG

US3692001

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) **13 Feb 2021 00:45:24**

Generated On: 10 Jun 2021 09:24:06

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)*	26 AUG 2020
Time of assessment *(00:00-23:59)*	17:48 (24 HR)
Vital Signs Date and Time (derived)	26 AUG 2020 17:48
Temperature *(xxx.x)*	36.1 C
Route of measurement	Oral ⬛
	Axillary ⬭
	Other ⬭
If Other, specify	
Pulse *(xxx)*	66 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	74 mmHg
Diastolic Blood Pressure units	MMHG

US3692001

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) **13 Feb 2021 00:45:24**

Generated On: 10 Jun 2021 09:24:06

Was the physical examination performed?   Yes ⬤

No ◯

Date of examination *(dd MMM yyyy)*   26 AUG 2020

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

US3692001

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) **13 Feb 2021 00:45:24**

Generated On: 10 Jun 2021 09:24:06

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)*	26 AUG 2020
What was the treatment time? *(00:00-23:59)*	17:17 (24 HR)
Treatment Date and Time (derived)	26 AUG 2020 17:17
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

US3692001

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) **13 Feb 2021 00:45:24**

Generated On: 10 Jun 2021 09:24:06

Was the sample collected?	Yes ⬤
	No ◯
Collection date *(dd MMM yyyy)*	26 AUG 2020
Collection time *(00:00-23:59)*	14:39 (24 HR)
Collection date and time (derived)	26 AUG 2020 14:39

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed:　(b) (4)　**13 Feb 2021 00:45:24**

Generated On: 10 Jun 2021 09:24:06

Collection date (dd MMM yyyy)			26 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:53	26 AUG 2020 14:53
Nasopharyngeal Swab 2	No		

US3692001
Folder: Visit 1 Day 1
Form: Continuing
Data signed: (b) (4) **13 Feb 2021 00:45:24**
Generated On: 10 Jun 2021 09:24:06

Is the participant continuing to the next visit?   Yes ●

                                                                                          No ○

Continuing Flag   1

US3692001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:24:06

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**	97.0 °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	26 AUG 2020 17:54
PC Open Date & Time	26 AUG 2020 17:37
PC Close Date & Time	26 AUG 2020 20:07

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○

Please record your **TEMPERATURE in °F**	97.9 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp	27 AUG 2020 10:30
PC Open Date & Time	26 AUG 2020 21:02
PC Close Date & Time	27 AUG 2020 11:59

US3692001

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:24:06

TIMEPOINT	DAY 2

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○

Please record your **TEMPERATURE in °F**	97.5 °F

Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp	27 AUG 2020 17:37
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

TIMEPOINT	DAY 3

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○

Please record your **TEMPERATURE in °F**	98.0 °F

Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp	28 AUG 2020 15:23
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

FDA-CBER-2022-1614-3321502

TIMEPOINT	DAY 4

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ⬤
	No ◯

Please record your **TEMPERATURE in °F**	98.0 °F

Was any **MEDICATION TAKEN today for pain or fever**?	Yes ◯
	No ⬤

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp	29 AUG 2020 19:33
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3692001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:24:06

TIMEPOINT	DAY 5

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	97.9 °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	30 AUG 2020 18:22
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3692001

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:24:06

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**	98.0 °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	31 AUG 2020 18:57
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3692001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:24:06

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**	98.1 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp	01 SEP 2020 17:55
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3692001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:24:06

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	26 AUG 2020 17:54
PC Open Date & Time	26 AUG 2020 17:37
PC Close Date & Time	26 AUG 2020 20:07

US3692001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:24:06

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	27 AUG 2020 10:31
PC Open Date & Time	26 AUG 2020 21:02
PC Close Date & Time	27 AUG 2020 11:59

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	27 AUG 2020 17:37
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

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	28 AUG 2020 15:23
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

FDA-CBER-2022-1614-3321510

US3692001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:24:06

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	29 AUG 2020 19:33
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3692001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:24:06

TIMEPOINT	DAY 5
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ⬤
	Does not interfere with activity ◯
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ◯
	Any use of prescription pain reliever or prevents daily activity ◯
Is there any **REDNESS AT INJECTION SITE**?	Yes ◯
	No ⬤
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ◯
	No ⬤
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ⬤
	Does not interfere with activity ◯
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ◯
	Any use of prescription pain reliever or prevents daily activity ◯
PC Time Stamp	30 AUG 2020 18:22
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

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	31 AUG 2020 18:58
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3692001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:24:06

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	01 SEP 2020 17:55
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3692001
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:24:06

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 ◯

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ⬤
	Yes ◯

PC Time stamp	26 AUG 2020 17:54
PC Open Date & Time	26 AUG 2020 17:37
PC Close Date & Time	26 AUG 2020 20:07

US3692001
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:24:06

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 ○

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ⬤
	Yes ◯

PC Time stamp	27 AUG 2020 10:31
PC Open Date & Time	26 AUG 2020 21:02
PC Close Date & Time	27 AUG 2020 11:59

US3692001
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:24:06

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 ●

	Yes ◯
PC Time stamp	27 AUG 2020 17:37
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3692001
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:24:06

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 ●

	Yes ◯
PC Time stamp	28 AUG 2020 15:23
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3692001
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:24:06

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 ●

	Yes ◯
PC Time stamp	29 AUG 2020 19:34
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3692001
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:24:06

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 ⬤

	Yes ◯
PC Time stamp	30 AUG 2020 18:22
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3692001
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:24:06

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 ●

	Yes ◯
PC Time stamp	31 AUG 2020 18:58
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3692001
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:24:06

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 ●

	Yes ◯
PC Time stamp	01 SEP 2020 17:56
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3692001

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) **13 Feb 2021 00:45:24**

Generated On: 10 Jun 2021 09:24:06

Was Contact Attempted?	Yes ●
	No ○
Date of Contact or Contact Attempt *(dd MMM yyyy)*	2 SEP 2020
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ○

Comments

If Contact Not Made, please provide Comments

US3692001

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) **13 Feb 2021 00:45:24**

Generated On: 10 Jun 2021 09:24:06

Is the participant continuing to the next visit?　　　　　　　　　　　　　　　Yes ⬤

　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　No ◯

Continuing Flag　　　　　　　　　　　　　　　　　　　　　　　　　　　　　1

US3692001
Folder: Safety Call Day 15 (1)
Form: Safety Call
Data signed: (b) (4) **13 Feb 2021 00:45:24**
Generated On: 10 Jun 2021 09:24:06

| Was Contact Attempted? | Yes ⬤ |
| | No ◯ |

Date of Contact or Contact Attempt *(dd MMM yyyy)*	9 SEP 2020
Please select one status for the follow-up contact	Contact Made ⬤
	Contact Not Made ◯

Comments

If Contact Not Made, please provide Comments

US3692001

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) **13 Feb 2021 00:45:24**

Generated On: 10 Jun 2021 09:24:06

Is the participant continuing to the next visit?   Yes ⬤

                                                                                     No ◯

Continuing Flag   1

US3692001
Folder: Safety Call Day 22 (1)
Form: Safety Call
Data signed: (b) (4) **13 Feb 2021 00:45:24**
Generated On: 10 Jun 2021 09:24:06

Was Contact Attempted?	Yes ⬤
	No ◯
Date of Contact or Contact Attempt *(dd MMM yyyy)*	16 SEP 2020
Please select one status for the follow-up contact	Contact Made ⬤
	Contact Not Made ◯

Comments

If Contact Not Made, please provide Comments

US3692001

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) **13 Feb 2021 00:45:24**

Generated On: 10 Jun 2021 09:24:06

Is the participant continuing to the next visit?   Yes ●

                                                                  No ◯

Continuing Flag   1

US3692001
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Data signed: (b) (4) **13 Feb 2021 00:45:24**
Generated On: 10 Jun 2021 09:24:06

Was this visit performed?	Yes ●
	No ○
Visit date (dd MMM yyyy)	23 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●
Folder OID	VISIT2

US3692001

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) **13 Feb 2021 00:45:24**

Generated On: 10 Jun 2021 09:24:06

Timepoint	Pre-Dose ⬤
	Post-Dose ◯
Were vital signs assessed?	Yes ⬤
	No ◯
Date of assessment *(dd MMM yyyy)*	23 SEP 2020
Time of assessment *(00:00-23:59)*	08:18 (24 HR)
Vital Signs Date and Time (derived)	23 SEP 2020 08:18
Temperature *(xxx.x)*	36.3 C
Route of measurement	Oral ⬤
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	75 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	78 mmHg
Diastolic Blood Pressure units	MMHG

Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Data signed: (b) (4) **13 Feb 2021 00:45:24**
Generated On: 10 Jun 2021 09:24:06

Timepoint	Pre-Dose ◯
	Post-Dose ⬤
Were vital signs assessed?	Yes ⬤
	No ◯
Date of assessment *(dd MMM yyyy)*	23 SEP 2020
Time of assessment *(00:00-23:59)*	10:28 (24 HR)
Vital Signs Date and Time (derived)	23 SEP 2020 10:28
Temperature *(xxx.x)*	36.7 C
Route of measurement	Oral ⬤
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	60 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	74 mmHg
Diastolic Blood Pressure units	MMHG

US3692001

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) **13 Feb 2021 00:45:24**

Generated On: 10 Jun 2021 09:24:06

Was the physical examination performed?   Yes ●

                                                                            No ◯

Date of examination *(dd MMM yyyy)*   23 SEP 2020

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

US3692001

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4)   **13 Feb 2021 00:45:24**

Generated On: 10 Jun 2021 09:24:06

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)*	23 SEP 2020
What was the treatment time? *(00:00-23:59)*	09:56 (24 HR)
Treatment Date and Time (derived)	23 SEP 2020 09:56
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

US3692001

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) **13 Feb 2021 00:45:24**

Generated On: 10 Jun 2021 09:24:06

Was the sample collected?	Yes	⬤
	No	◯

Collection date *(dd MMM yyyy)*	23 SEP 2020
Collection time *(00:00-23:59)*	09:06 (24 HR)
Collection date and time (derived)	23 SEP 2020 09:06

US3692001

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) **13 Feb 2021 00:45:24**

Generated On: 10 Jun 2021 09:24:06

Collection date *(dd MMM yyyy)*			23 SEP 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:12	23 SEP 2020 09:12
Nasopharyngeal Swab 2	No		

US3692001

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) **13 Feb 2021 00:45:24**

Generated On: 10 Jun 2021 09:24:06

Is the participant continuing to the next visit?   Yes ⬤

                                                                                                          No ◯

Continuing Flag   1

US3692001
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:24:06

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	98.0 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp	23 SEP 2020 10:28
PC Open Date & Time	23 SEP 2020 10:16
PC Close Date & Time	23 SEP 2020 12:46

FDA-CBER-2022-1614-3321545

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	98.3 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp	23 SEP 2020 18:39
PC Open Date & Time	23 SEP 2020 13:41
PC Close Date & Time	24 SEP 2020 11:59

US3692001
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:24:06

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**	98.2 °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	24 SEP 2020 20:34
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3692001
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:24:06

| **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**	98.4 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	25 SEP 2020 20:52
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

PRODUCTION RELEASE (v12.003 EAB) (1725)

73 of 2235

FDA-CBER-2022-1614-3321548

US3692001

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:24:06

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**	98.3 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	26 SEP 2020 20:59
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3692001

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:24:06

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**	98.3 °F

Was any **MEDICATION TAKEN today for pain or fever**?	Yes ◯
	No ⬤

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp	27 SEP 2020 20:22
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3692001
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:24:06

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**	98.5 °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	28 SEP 2020 21:10
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3692001

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:24:06

TIMEPOINT	DAY 7

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	97.7 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp	29 SEP 2020 12:00
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3692001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:24:06

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	23 SEP 2020 10:29
PC Open Date & Time	23 SEP 2020 10:16
PC Close Date & Time	23 SEP 2020 12:46

US3692001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:24:06

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	23 SEP 2020 18:39
PC Open Date & Time	23 SEP 2020 13:41
PC Close Date & Time	24 SEP 2020 11:59

US3692001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:24:06

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	24 SEP 2020 20:34
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

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	25 SEP 2020 20:52
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3692001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:24:06

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	26 SEP 2020 21:00
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3692001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:24:06

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	27 SEP 2020 20:23
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3692001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:24:06

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	28 SEP 2020 21:10
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

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	29 SEP 2020 12:00
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3692001
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:24:06

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 ◯

US3692001
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:24:06

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ●
	Yes ○

PC Time stamp	23 SEP 2020 10:29
PC Open Date & Time	23 SEP 2020 10:16
PC Close Date & Time	23 SEP 2020 12:46

US3692001
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:24:06

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)

HEADACHE

None	●
No interference with activity	◯
Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity	◯
Any use of prescription pain reliever or prevents daily activity	◯

FATIGUE

None	●
No interference with activity	◯
Some interference with activity	◯
Significant; prevents daily activity	◯

MUSCLE ACHES ALL OVER BODY

None	●
No interference with activity	◯
Some interference with activity	◯
Significant; prevents daily activity	◯

JOINT ACHES IN SEVERAL JOINTS

None	●
No interference with activity	◯
Some interference with activity	◯
Significant; prevents daily activity	◯

NAUSEA/VOMITING

None	●
No interference with activity or 1-2 episodes/24 hours	◯
Some interference with activity or >2 episodes/24 hours	◯
Prevents daily activity, requires outpatient IV hydration	◯

CHILLS

None	●
No interference with activity	◯
Some interference with activity not requiring medical attention	◯
Prevents daily activity and requires medical attention	◯

FDA-CBER-2022-1614-3321563

| Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms? | No ⬤ |
| | Yes ◯ |

PC Time stamp	23 SEP 2020 18:40
PC Open Date & Time	23 SEP 2020 13:41
PC Close Date & Time	24 SEP 2020 11:59

US3692001
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:24:06

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-2022-1614-3321565

	Yes ◯
PC Time stamp	24 SEP 2020 20:34
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3692001
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:24:06

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 ⬤

	Yes ◯
PC Time stamp	25 SEP 2020 20:52
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3692001
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:24:06

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 ●

	Yes ⭕
PC Time stamp	26 SEP 2020 21:00
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

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-2022-1614-3321571

US3692001
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:24:06

	Yes ◯
PC Time stamp	27 SEP 2020 20:23
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3692001
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:24:06

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 ⬤

	Yes ◯
PC Time stamp	28 SEP 2020 21:11
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3692001
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:24:06

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 ●

	Yes ◯
PC Time stamp	29 SEP 2020 12:00
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3692001

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) **13 Feb 2021 00:45:24**

Generated On: 10 Jun 2021 09:24:06

Was Contact Attempted?	Yes ●
	No ◯
Date of Contact or Contact Attempt *(dd MMM yyyy)*	30 SEP 2020
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ◯
Comments	NO AE OR COVID SYMPTOMS REPORTED ON EDIARY.
If Contact Not Made, please provide Comments	PARTICIPANT REPORTS NO HEALTH CHANGES.

US3692001

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) **13 Feb 2021 00:45:24**

Generated On: 10 Jun 2021 09:24:06

Is the participant continuing to the next visit?	Yes ●
	No ○

Continuing Flag   1

US3692001

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) **13 Feb 2021 00:45:24**

Generated On: 10 Jun 2021 09:24:06

Was Contact Attempted?	Yes ●
	No ○
Date of Contact or Contact Attempt *(dd MMM yyyy)*	07 OCT 2020
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ○
Comments	PARTICIPANT REPORTS NO CHANGES SINCE LAST STUDY CONTACT.
If Contact Not Made, please provide Comments	

US3692001

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) **13 Feb 2021 00:45:24**

Generated On: 10 Jun 2021 09:24:06

Is the participant continuing to the next visit?   Yes ⬤

    No ◯

Continuing Flag   1

US3692001
Folder: Safety Call Day 50 (1)
Form: Safety Call
Data signed: (b) (4) **13 Feb 2021 00:45:24**
Generated On: 10 Jun 2021 09:24:06

Was Contact Attempted?	Yes ●
	No ○

Date of Contact or Contact Attempt *(dd MMM yyyy)*	15 OCT 2020
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ○

Comments

If Contact Not Made, please provide Comments

US3692001

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) **13 Feb 2021 00:45:24**

Generated On: 10 Jun 2021 09:24:06

Is the participant continuing to the next visit?   Yes ⬤

                                                                                    No ◯

Continuing Flag   1

US3692001
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Data signed: (b) (4) **13 Feb 2021 00:45:24**
Generated On: 10 Jun 2021 09:24:06

Was this visit performed?	Yes ●
	No ○
Visit date (dd MMM yyyy)	23 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●
Folder OID	VISIT3

US3692001
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Data signed: (b) (4) **13 Feb 2021 00:45:24**
Generated On: 10 Jun 2021 09:24:06

Were vital signs assessed?	Yes ●
	No ◯
Date of assessment *(dd MMM yyyy)*	23 OCT 2020
Time of assessment *(00:00-23:59)*	8:30 (24 HR)
Vital Signs Date and Time (derived)	23 OCT 2020 8:30
Temperature *(xxx.x)*	36.4 C
Route of measurement	Oral ●
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	69 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	69 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3692001

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) **13 Feb 2021 00:45:24**

Generated On: 10 Jun 2021 09:24:06

Was the physical examination performed? Yes ◯

No ●

Date of examination *(dd MMM yyyy)* _____

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

Was the sample collected?	Yes ●
	No ○
Collection date *(dd MMM yyyy)*	23 OCT 2020
Collection time *(00:00-23:59)*	8:48 (24 HR)
Collection date and time (derived)	23 OCT 2020 8:48

US3692001

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) **13 Feb 2021 00:45:24**

Generated On: 10 Jun 2021 09:24:06

Is the participant continuing to the next visit?   Yes ●

No ○

Continuing Flag   1

US3692001

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

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	26 OCT 2020 08:21:52
Patient Cloud Open Date & Time	26 OCT 2020 00:01
Patient Cloud Close Date & Time	30 OCT 2020 23:59

US3692001

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

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	02 NOV 2020 08:52:40
Patient Cloud Open Date & Time	02 NOV 2020 00:01
Patient Cloud Close Date & Time	06 NOV 2020 23:59

US3692001

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

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	09 NOV 2020 10:04:26
Patient Cloud Open Date & Time	09 NOV 2020 00:01
Patient Cloud Close Date & Time	13 NOV 2020 23:59

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 NOV 2020 07:40:22
Patient Cloud Open Date & Time	20 NOV 2020 00:01
Patient Cloud Close Date & Time	24 NOV 2020 23:59

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ◯
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 DEC 2020 19:25:11
Patient Cloud Open Date & Time	27 NOV 2020 00:01
Patient Cloud Close Date & Time	01 DEC 2020 23:59

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

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	04 DEC 2020 15:58:30
Patient Cloud Open Date & Time	04 DEC 2020 00:01
Patient Cloud Close Date & Time	08 DEC 2020 23:59

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 DEC 2020 13:27:36
Patient Cloud Open Date & Time	11 DEC 2020 00:01
Patient Cloud Close Date & Time	15 DEC 2020 23:59

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⚪ Yes ⬤
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ⚪
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ⚪
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⚪ Yes ⬤
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬤
Date and time of submission	18 DEC 2020 16:59:49
Patient Cloud Open Date & Time	18 DEC 2020 00:01
Patient Cloud Close Date & Time	22 DEC 2020 23:59

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	25 DEC 2020 00:01:40
Patient Cloud Open Date & Time	25 DEC 2020 00:01
Patient Cloud Close Date & Time	29 DEC 2020 23:59

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ◯
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 JAN 2021 00:12:26
Patient Cloud Open Date & Time	01 JAN 2021 00:01
Patient Cloud Close Date & Time	05 JAN 2021 23:59

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤
	Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤
	Yes ◯
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	09 JAN 2021 08:40:31
Patient Cloud Open Date & Time	08 JAN 2021 00:01
Patient Cloud Close Date & Time	12 JAN 2021 23:59

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ◯
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 JAN 2021 20:35:58
Patient Cloud Open Date & Time	15 JAN 2021 00:01
Patient Cloud Close Date & Time	19 JAN 2021 23:59

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ◯
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 JAN 2021 08:16:40
Patient Cloud Open Date & Time	22 JAN 2021 00:01
Patient Cloud Close Date & Time	26 JAN 2021 23:59

FDA-CBER-2022-1614-3321600

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	31 JAN 2021 09:46:15
Patient Cloud Open Date & Time	29 JAN 2021 00:01
Patient Cloud Close Date & Time	02 FEB 2021 23:59

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ◯
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 FEB 2021 00:01:31
Patient Cloud Open Date & Time	05 FEB 2021 00:01
Patient Cloud Close Date & Time	09 FEB 2021 23:59

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

TIMEPOINT	DAY 173
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 FEB 2021 00:01:19
Patient Cloud Open Date & Time	12 FEB 2021 00:01
Patient Cloud Close Date & Time	16 FEB 2021 23:59

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 FEB 2021 14:40:00
Patient Cloud Open Date & Time	19 FEB 2021 00:01
Patient Cloud Close Date & Time	23 FEB 2021 23:59

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ◯
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	26 FEB 2021 07:00:30
Patient Cloud Open Date & Time	26 FEB 2021 00:01
Patient Cloud Close Date & Time	02 MAR 2021 23:59

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 MAR 2021 07:34:30
Patient Cloud Open Date & Time	05 MAR 2021 00:01
Patient Cloud Close Date & Time	09 MAR 2021 23:59

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ◯
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 MAR 2021 10:49:33
Patient Cloud Open Date & Time	12 MAR 2021 00:01
Patient Cloud Close Date & Time	16 MAR 2021 23:59

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

TIMEPOINT	DAY 208
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 MAR 2021 13:51:49
Patient Cloud Open Date & Time	19 MAR 2021 00:01
Patient Cloud Close Date & Time	23 MAR 2021 23:59

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 MAR 2021 14:32:51
Patient Cloud Open Date & Time	26 MAR 2021 00:01
Patient Cloud Close Date & Time	30 MAR 2021 23:59

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ◯
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 APR 2021 16:55:57
Patient Cloud Open Date & Time	02 APR 2021 00:01
Patient Cloud Close Date & Time	06 APR 2021 23:59

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ● Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	09 APR 2021 06:42:53
Patient Cloud Open Date & Time	09 APR 2021 00:01
Patient Cloud Close Date & Time	13 APR 2021 23:59

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	16 APR 2021 00:02:26
Patient Cloud Open Date & Time	16 APR 2021 00:01
Patient Cloud Close Date & Time	20 APR 2021 23:59

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ◯
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 APR 2021 16:46:38
Patient Cloud Open Date & Time	23 APR 2021 00:01
Patient Cloud Close Date & Time	27 APR 2021 23:59

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	30 APR 2021 07:46:30
Patient Cloud Open Date & Time	30 APR 2021 00:01
Patient Cloud Close Date & Time	04 MAY 2021 23:59

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

TIMEPOINT	**DAY 257**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

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

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

TIMEPOINT	**DAY 264**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Symptom	
Fever (Temperature $\geq$ 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 ⬭

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

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

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

TIMEPOINT   DAY 271

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq$ 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-2022-1614-3321619

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

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

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

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 $\geq$ 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-2022-1614-3321621

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

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

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

TIMEPOINT	**DAY 285**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⚪ Yes ⚪
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⚪ Yes ⚪
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⚪
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⚪ Yes ⚪

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq$ 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-2022-1614-3321623

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

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

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

TIMEPOINT	**DAY 292**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq$ 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 ◯

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

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

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

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 $\geq$ 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 ◯

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

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

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

TIMEPOINT   DAY 306

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq$ 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-2022-1614-3321629

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

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

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

TIMEPOINT DAY 313

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq$ 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-2022-1614-3321631

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

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

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

TIMEPOINT	**DAY 320**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕
	Yes ⭕
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕
	Yes ⭕
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⭕
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕
	Yes ⭕

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⭕
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕
	Yes ⭕

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

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

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

TIMEPOINT	DAY 327

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq$ 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 ◯

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

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

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

TIMEPOINT	**DAY 334**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq$ 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 ◯

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

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

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

TIMEPOINT	**DAY 341**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq$ 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 ◯

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

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

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

TIMEPOINT	**DAY 348**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Symptom	
Fever (Temperature $\geq$ 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 ◯

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

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

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

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 $\geq$ 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 ◯

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06

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

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

TIMEPOINT	DAY 362

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq$ 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 ◯

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2021 00:01
Patient Cloud Close Date & Time	24 AUG 2021 23:59

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

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):

Symptom	
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 ◯

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

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

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

TIMEPOINT   DAY 376

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⚪ Yes ⚪
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⚪ Yes ⚪
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⚪
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⚪ Yes ⚪

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq$ 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-2022-1614-3321649

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

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

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

TIMEPOINT	DAY 383
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq$ 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 ◯

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

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

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

TIMEPOINT	**DAY 390**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq$ 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 ◯

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

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

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

TIMEPOINT   DAY 397

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq$ 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 ◯

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06

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

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

TIMEPOINT   DAY 404

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq$ 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 ◯

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

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

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

TIMEPOINT DAY 411

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ○ Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ○ Yes ○
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ○
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ○ Yes ○

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ○
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ○ Yes ○

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

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

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

TIMEPOINT	DAY 418

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

FDA-CBER-2022-1614-3321661

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

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

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

TIMEPOINT	**DAY 425**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

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

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

TIMEPOINT   DAY 432

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⭕
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⭕
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

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

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

TIMEPOINT	**DAY 439**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Symptom	
Fever (Temperature $\geq$ 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 ◯

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06

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

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

TIMEPOINT DAY 446

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature ≥ 100.4°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

FDA-CBER-2022-1614-3321669

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

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

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

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-2022-1614-3321671

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

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

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq$ 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-2022-1614-3321673

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

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

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

TIMEPOINT   DAY 467

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⭕
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq$ 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-2022-1614-3321675

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

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

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

TIMEPOINT	DAY 474

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

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

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

TIMEPOINT DAY 481

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq$ 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 ◯

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

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

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

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-2022-1614-3321681

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

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

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

TIMEPOINT	**DAY 495**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq$ 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 ◯

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	31 DEC 2021 00:01
Patient Cloud Close Date & Time	04 JAN 2022 23:59

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

TIMEPOINT   DAY 502

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq$ 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-2022-1614-3321685

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

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

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

TIMEPOINT	DAY 509
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 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 ◯

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

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

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq$ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

TIMEPOINT DAY 523

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Symptom	
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-2022-1614-3321691

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

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

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

TIMEPOINT	**DAY 530**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⃝
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Symptom	
Fever (Temperature $\geq$ 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-2022-1614-3321693

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

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

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

TIMEPOINT DAY 537

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq$ 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 ◯

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

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

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

TIMEPOINT	**DAY 544**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Symptom	
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 ◯

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

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

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

TIMEPOINT	**DAY 551**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

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

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

TIMEPOINT   DAY 558

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq$ 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-2022-1614-3321701

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

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

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

TIMEPOINT	**DAY 565**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

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

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

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 $\geq$ 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-2022-1614-3321705

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

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

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

TIMEPOINT **DAY 579**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Symptom	
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-2022-1614-3321707

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

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

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

TIMEPOINT	**DAY 586**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⃝
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⃝
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⃝ Yes ⃝

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

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

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

TIMEPOINT	DAY 593
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⭘ Yes ⭘
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⭘ Yes ⭘
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⭘
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⭘ Yes ⭘

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⭘
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ⭘ Yes ⭘

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

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

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

TIMEPOINT	DAY 600

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

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

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

TIMEPOINT   DAY 607

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯
	Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq$ 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-2022-1614-3321715

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

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

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

TIMEPOINT	DAY 614

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

FDA-CBER-2022-1614-3321717

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06

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

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

TIMEPOINT DAY 621

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq$ 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 ◯

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

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

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ○ Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ○ Yes ○
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ○
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ○ Yes ○

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq$ 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 ○

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

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

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq$ 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-2022-1614-3321723

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

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

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

TIMEPOINT   **DAY 642**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq$ 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-2022-1614-3321725

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

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

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Symptom	
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 ◯

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

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

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

TIMEPOINT	**DAY 656**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

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

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

TIMEPOINT	**DAY 663**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Symptom	
Fever (Temperature $\geq$ 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 ◯

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

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

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

TIMEPOINT DAY 670

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq$ 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-2022-1614-3321733

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

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

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

TIMEPOINT	DAY 677
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq$ 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 ◯

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

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

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

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-2022-1614-3321737

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

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

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

TIMEPOINT   DAY 691

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Symptom	
Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

TIMEPOINT   DAY 698

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Symptom	
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 ◯

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

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

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

TIMEPOINT   DAY 705

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq$ 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 ⬭

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	29 JUL 2022 00:01
Patient Cloud Close Date & Time	02 AUG 2022 23:59

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

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 ⬭

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

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

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⭕
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Symptom	
Fever (Temperature $\geq$ 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-2022-1614-3321747

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

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

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

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 $\geq$ 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-2022-1614-3321749

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

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

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

TIMEPOINT DAY 733

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq$ 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 ⬭

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

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

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

TIMEPOINT   DAY 740

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

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

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

TIMEPOINT DAY 747

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq$ 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 ◯

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

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

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq$ 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 ◯

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

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

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

TIMEPOINT	**DAY 761**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Symptom	
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 ◯

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

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

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

TIMEPOINT   DAY 768

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq$ 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 ⬭

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

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

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

TIMEPOINT	**DAY 775**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq$ 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 ◯

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

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

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

TIMEPOINT	DAY 782
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⚪ Yes ⚪
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⚪ Yes ⚪
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⚪
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⚪ Yes ⚪

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq$ 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 ⚪

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

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

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

TIMEPOINT   DAY 789

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Symptom	
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-2022-1614-3321767

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

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

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

TIMEPOINT	**DAY 796**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature ≥ 100.4°F/38°C)	_____
Chills	_____
Cough	_____
Shortness of breath	_____
Difficulty breathing	_____
Fatigue	_____
Muscle aches	_____
Body aches	_____
Headache	_____
New loss of taste	_____
New loss of smell	_____
Sore throat	_____
Congestion	_____
Runny nose	_____
Nausea	_____
Vomiting	_____
Diarrhea	_____
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

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

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission	
No		05 MAR 2021 07:34:46	

US3692001
Folder: Safety Call Day 85 (1)
Form: Safety Call
Data signed: (b) (4) **19 Feb 2021 23:32:09**
Generated On: 10 Jun 2021 09:24:06

| Was Contact Attempted? | Yes ● |
| | No ○ |

Date of Contact or Contact Attempt *(dd MMM yyyy)*   17 NOV 2020

| Please select one status for the follow-up contact | Contact Made ● |
| | Contact Not Made ○ |

Comments

If Contact Not Made, please provide Comments

US3692001

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) **19 Feb 2021 23:32:09**

Generated On: 10 Jun 2021 09:24:06

Is the participant continuing to the next visit?   Yes ⬤

No ◯

Continuing Flag   1

US3692001

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) **19 Feb 2021 23:32:09**

Generated On: 10 Jun 2021 09:24:06

| Was Contact Attempted? | Yes ● |
| | No ○ |

| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 22 DEC 2020 |

| Please select one status for the follow-up contact | Contact Made ● |
| | Contact Not Made ○ |

Comments

If Contact Not Made, please provide Comments

PT HOSPITALIZED FOR GASTRIC ULCERS FROM 14 DEC - 16 DEC. CHART AND COMMUNICATIONS ADDED TO PT CHART. NEW MEDS AND PROCEDURE ADDED. NEW CONSENT REVIEWED AND SIGNED.

US3692001

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) **19 Feb 2021 23:32:09**

Generated On: 10 Jun 2021 09:24:06

Is the participant continuing to the next visit?   Yes ●

No ◯

Continuing Flag   1

US3692001

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) **19 Feb 2021 23:32:09**

Generated On: 10 Jun 2021 09:24:06

| Was Contact Attempted? | Yes ● |
| | No ○ |

Date of Contact or Contact Attempt *(dd MMM yyyy)*	18 JAN 2021
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ○

Comments

If Contact Not Made, please provide Comments

US3692001

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) **19 Feb 2021 23:32:09**

Generated On: 10 Jun 2021 09:24:06

Is the participant continuing to the next visit?   Yes ●

                                                                                                        No ◯

Continuing Flag   1

US3692001

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) **19 Feb 2021 23:32:09**

Generated On: 10 Jun 2021 09:24:06

Was Contact Attempted?	Yes ⬤
	No ◯

Date of Contact or Contact Attempt *(dd MMM yyyy)*	18 FEB 2021
Please select one status for the follow-up contact	Contact Made ⬤
	Contact Not Made ◯

Comments

If Contact Not Made, please provide Comments

US3692001

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) **19 Feb 2021 23:32:09**

Generated On: 10 Jun 2021 09:24:06

Is the participant continuing to the next visit?   Yes ⬤

                                                                                     No ◯

Continuing Flag   1

US3692001
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Data signed: (b) (4) **19 Mar 2021 19:59:42**
Generated On: 10 Jun 2021 09:24:06

Was this visit performed?	Yes ●
	No ○
Visit date (dd MMM yyyy)	19 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●
Folder OID	VISIT4

US3692001

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) **01 Apr 2021 21:15:32**

Generated On: 10 Jun 2021 09:24:06

Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	19 MAR 2021
Time of assessment *(00:00-23:59)*	09:32 (24 HR)
Vital Signs Date and Time (derived)	19 MAR 2021 09:32
Temperature *(xxx.x)*	36.9 C
Route of measurement	Oral ●
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	73 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	81 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

FDA-CBER-2022-1614-3321781

US3692001

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4)   **19 Mar 2021 19:59:42**

Generated On: 10 Jun 2021 09:24:06

Was the physical examination performed?   Yes ◯

                                                                           No ⬤

Date of examination *(dd MMM yyyy)*   _____

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

Was the sample collected?	Yes ⬤
	No ◯
Collection date *(dd MMM yyyy)*	19 MAR 2021
Collection time *(00:00-23:59)*	09:44 (24 HR)
Collection date and time (derived)	19 MAR 2021 09:44

US3692001

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) **19 Mar 2021 19:59:42**

Generated On: 10 Jun 2021 09:24:06

Is the participant continuing to the next visit?   Yes ●

No ◯

Continuing Flag   1

US3692001
Folder: Safety Call Day 239 (1)
Form: Safety Call
Data signed: (b) (4) **22 Apr 2021 18:26:17**
Generated On: 10 Jun 2021 09:24:06

| Was Contact Attempted? | Yes ● |
| | No ○ |

| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 19 APR 2021 |

| Please select one status for the follow-up contact | Contact Made ● |
| | Contact Not Made ○ |

Comments

If Contact Not Made, please provide Comments

US3692001

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) **22 Apr 2021 18:26:17**

Generated On: 10 Jun 2021 09:24:06

Is the participant continuing to the next visit?   Yes ⬤

                                                                                No ◯

Continuing Flag   1

US3692001
Folder: Safety Call Day 269 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:24:06

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

US3692001
Folder: Covid-19 Assessment (1)
Form: COVID-19 Contact
Generated On: 10 Jun 2021 09:24:06

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 ⚪

| Generate Next COVID-19 Assessment | Yes $\bigcirc$ |
| | No $\bigcirc$ |

US3692001

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Data signed: (b) (4) **19 Feb 2021 23:32:08**

Generated On: 10 Jun 2021 09:24:06

Was this visit performed?	Yes ●
	No ○

Visit date (dd MMM yyyy)	9 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●

Folder OID	UNBLND_DECIDE

Date of updated informed consent *(dd MMM yyyy)*	9 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes ●
	No ○
Under what version of the Protocol was the Participant unblinded?	Amendment 5 ○
	Amendment 6 or later ●
Date of unblinding *(dd MMM yyyy)*	9 JAN 2021
Participant randomization assignment	mRNA-1273 ○
	Placebo ●
Actual Dose 1	mRNA-1273 ○
	Placebo ●
	Not Administered ○
Actual Dose 2	mRNA-1273 ○
	Placebo ●
	Not Administered ○
Will participant receive mRNA-1273?	Yes ●
	No ○
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3692001

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Data signed: (b) (4) **05 Mar 2021 20:57:21**

Generated On: 10 Jun 2021 09:24:06

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

US3692001

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4)　05 Mar 2021 20:57:21

Generated On: 10 Jun 2021 09:24:06

Height	ND - Not Done
Weight	ND - Not Done
BMI *(xxx.x)*	
Timepoint	Pre-Dose ⬤
	Post-Dose ◯
Were vital signs assessed?	Yes ⬤
	No ◯
Date of assessment *(dd MMM yyyy)*	11 JAN 2021
Time of assessment *(00:00-23:59)*	10:53 (24 HR)
Vital Signs Date and Time (derived)	11 JAN 2021 10:53
Temperature *(xxx.x)*	36.3 C
Route of measurement	Oral ⬤
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	73 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	75 mmHg
Diastolic Blood Pressure units	MMHG

US3692001

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) **05 Mar 2021 20:57:21**

Generated On: 10 Jun 2021 09:24:06

Height	ND - Not Done
Weight	ND - Not Done
BMI *(xxx.x)*	
Timepoint	Pre-Dose ◯
	Post-Dose ⬤
Were vital signs assessed?	Yes ⬤
	No ◯
Date of assessment *(dd MMM yyyy)*	11 JAN 2021
Time of assessment *(00:00-23:59)*	12:33 (24 HR)
Vital Signs Date and Time (derived)	11 JAN 2021 12:33
Temperature *(xxx.x)*	36.8 C
Route of measurement	Oral ⬤
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	60 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	111 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	76 mmHg
Diastolic Blood Pressure units	MMHG

US3692001

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Data signed: (b) (4)   **19 Feb 2021 23:32:08**

Generated On: 10 Jun 2021 09:24:06

Was the physical examination performed?   Yes ●

No ○

Date of examination *(dd MMM yyyy)*   9 JAN 2021

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

Was study treatment given?   Yes ⬤

                                                                                 No ◯

If No, reason not given   Participant declined due to ◯
                                                                    Adverse Event

                                                    Physician withheld dose due to ◯
                                                                    Adverse Event

                                                                            Death ◯

                                                                 Lost To Follow-Up ◯

                                                                 Physician Decision ◯

                                                                        Pregnancy ◯

                                                                Protocol Deviation ◯

                                                        Study Terminated by Sponsor ◯

                                                          Withdrawal of Consent by ◯
                                                                    Participant

                                                              Confirmed COVID-19 ◯

                                                                             Other ◯

If reason is Physician Decision, Withdrawal of Consent by
Participant, Protocol Deviation, or Other, specify

What was the study treatment? (Unblinded)	MRNA-1273
What was the treatment date? *(dd MMM yyyy)*	11 JAN 2021
What was the treatment time? *(00:00-23:59)*	12:03 (24 HR)
Treatment Date and Time (derived)	11 JAN 2021 12:03

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

US3692001

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) **19 Feb 2021 23:32:08**

Generated On: 10 Jun 2021 09:24:06

Was the sample collected?	Yes ⬤
	No ◯
Collection date *(dd MMM yyyy)*	9 JAN 2021
Collection time *(00:00-23:59)*	10:30 (24 HR)
Collection date and time (derived)	9 JAN 2021 10:30

US3692001

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) **19 Feb 2021 23:32:08**

Generated On: 10 Jun 2021 09:24:06

Was the sample collected?	Yes ●
	No ○
Collection date *(dd MMM yyyy)*	9 JAN 2021
Collection time *(00:00 - 23:59)*	10:35
Collection Date and Time (derived)	9 JAN 2021 10:35

US3692001

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Data signed: (b) (4) **19 Feb 2021 23:32:08**

Generated On: 10 Jun 2021 09:24:06

Is the participant continuing to the next visit?　　　　　　　　　Yes ⬤

　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　No ◯

Continuing Flag　　　　　　　　　　　　　　　　　　　　　　　　　1

US3692001

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) **19 Feb 2021 23:32:09**

Generated On: 10 Jun 2021 09:24:06

Was Contact Attempted?	Yes ●
	No ○
Date of Contact or Contact Attempt *(dd MMM yyyy)*	18 JAN 2021
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ○

Comments

If Contact Not Made, please provide Comments

US3692001

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) **19 Feb 2021 23:32:09**

Generated On: 10 Jun 2021 09:24:06

Is the participant continuing to the next visit?	Yes ⬤
	No ◯

Continuing Flag	1
OLD29 Placebo Flag	1

US3692001
Folder: OL-D29 (1)
Form: Visit Date
Data signed: (b) (4) **19 Feb 2021 23:32:08**
Generated On: 10 Jun 2021 09:24:06

Was this visit performed?	Yes ●
	No ○
Visit date (dd MMM yyyy)	08 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●
Folder OID	OLD29

US3692001

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) **19 Feb 2021 23:32:08**

Generated On: 10 Jun 2021 09:24:06

Timepoint	Pre-Dose ●
	Post-Dose ○
Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	08 FEB 2021
Time of assessment *(00:00-23:59)*	12:29 (24 HR)
Vital Signs Date and Time (derived)	08 FEB 2021 12:29
Temperature *(xxx.x)*	36.9 C
Route of measurement	Oral ●
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	61 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	65 mmHg
Diastolic Blood Pressure units	MMHG

US3692001

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) **19 Feb 2021 23:32:08**

Generated On: 10 Jun 2021 09:24:06

Timepoint	Pre-Dose ◯
	Post-Dose ⬤
Were vital signs assessed?	Yes ⬤
	No ◯
Date of assessment *(dd MMM yyyy)*	08 FEB 2021
Time of assessment *(00:00-23:59)*	13:24 (24 HR)
Vital Signs Date and Time (derived)	08 FEB 2021 13:24
Temperature *(xxx.x)*	36.8 C
Route of measurement	Oral ⬤
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	58 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	74 mmHg
Diastolic Blood Pressure units	MMHG

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) **19 Feb 2021 23:32:08**

Generated On: 10 Jun 2021 09:24:06

Was the physical examination performed?   Yes ●

                                                                          No ○

Date of examination *(dd MMM yyyy)*   08 FEB 2021

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

Was study treatment given?   Yes ⬤

                                                              No ◯

If No, reason not given   Participant declined due to ◯
                                             Adverse Event

                              Physician withheld dose due to ◯
                                             Adverse Event

                                                    Death ◯

                                           Lost To Follow-Up ◯

                                           Physician Decision ◯

                                                 Pregnancy ◯

                                          Protocol Deviation ◯

                                  Study Terminated by Sponsor ◯

                                     Withdrawal of Consent by ◯
                                                  Participant

                                        Confirmed COVID-19 ◯

                                                    Other ◯

If reason is Physician Decision, Withdrawal of Consent by
Participant, Protocol Deviation, or Other, specify

What was the study treatment? (Unblinded)	MRNA-1273
What was the treatment date? *(dd MMM yyyy)*	08 FEB 2021
What was the treatment time? *(00:00-23:59)*	12:54 (24 HR)
Treatment Date and Time (derived)	08 FEB 2021 12:54

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

US3692001

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) **19 Feb 2021 23:32:08**

Generated On: 10 Jun 2021 09:24:06

Is the participant continuing to the next visit?   Yes ⬤

                                                                    No ◯

Continuing Flag   1

US3692001

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) **19 Feb 2021 23:32:09**

Generated On: 10 Jun 2021 09:24:06

Was Contact Attempted?   Yes ●

                                                                         No ◯

Date of Contact or Contact Attempt *(dd MMM yyyy)*   15 FEB 2021

Please select one status for the follow-up contact   Contact Made ●

                                                         Contact Not Made ◯

Comments

If Contact Not Made, please provide Comments

US3692001

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4)   **19 Feb 2021 23:32:09**

Generated On: 10 Jun 2021 09:24:06

Is the participant continuing to the next visit?   Yes ●

No ◯

Continuing Flag   1

US3692001

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) **19 Mar 2021 19:59:42**

Generated On: 10 Jun 2021 09:24:06

Was this visit performed?	Yes ●
	No ○
Visit date (dd MMM yyyy)	19 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●
Folder OID	OLD57

US3692001

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) **19 Mar 2021 19:59:42**

Generated On: 10 Jun 2021 09:24:06

Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	19 MAR 2021
Time of assessment *(00:00-23:59)*	09:32 (24 HR)
Vital Signs Date and Time (derived)	19 MAR 2021 09:32
Temperature *(xxx.x)*	36.9 C
Route of measurement	Oral ●
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	73 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	81 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

Was the physical examination performed?   Yes ◯
                                                                                                             No ⬤

Date of examination *(dd MMM yyyy)*

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

Was the sample collected?	Yes ⬤
	No ◯
Collection date *(dd MMM yyyy)*	19 MAR 2021
Collection time *(00:00-23:59)*	09:44 (24 HR)
Collection date and time (derived)	19 MAR 2021 09:44

US3692001

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) **19 Feb 2021 23:32:08**

Generated On: 10 Jun 2021 09:24:06

Did the participant experience any adverse events?   Yes ⬤

    No ◯

If Yes, enter details on the Adverse Events form.

US3692001

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) **08 Apr 2021 14:22:33**

Generated On: 10 Jun 2021 09:24:06

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

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False

Relationship to investigational product	Not Related ●
	Related ○
	Not Applicable ○

Relationship to Study Procedure	Not Related ●
	Related ○
	Not Applicable ○

Action taken with investigational product	None ●
	Dose Delayed ○
	Investigational Product Withdrawn ○
	Not Applicable ○

Other action taken (check all that apply)

None	True
Concomitant Medication	False
Concomitant Procedure	False

Outcome	Fatal ○
	Not Recovered/Not Resolved ○
	Recovered/Resolved ●
	Recovered/Resolved with Sequelae ○
	Recovering/Resolving ○
	Unknown ○

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Ony)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	0

US3692001

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 08 Apr 2021 14:22:33

Generated On: 10 Jun 2021 09:24:06

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

FDA-CBER-2022-1614-3321818

US3692001

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) **08 Apr 2021 14:22:33**

Generated On: 10 Jun 2021 09:24:06

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False

Relationship to investigational product
- Not Related ●
- Related ○
- Not Applicable ○

Relationship to Study Procedure
- Not Related ●
- Related ○
- Not Applicable ○

Action taken with investigational product
- None ●
- Dose Delayed ○
- Investigational Product Withdrawn ○
- Not Applicable ○

Other action taken (check all that apply)

None	True
Concomitant Medication	False
Concomitant Procedure	False

Outcome
- Fatal ○
- Not Recovered/Not Resolved ○
- Recovered/Resolved ●
- Recovered/Resolved with Sequelae ○
- Recovering/Resolving ○
- Unknown ○

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Ony)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

AEID	
Adverse event	TACHYPNEA
Was this a medically-attended AE?	Yes ◯
	No ⬤
Was this a Solicited Adverse Reaction?	Yes ◯
	No ⬤
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ◯
	No ⬤
Start date *(dd MMM yyyy)*	26 AUG 2020
Start time *(00:00-23:59)*	17:48 (24 HR)
AE start date and time (derived)	26 AUG 2020 17:48
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, end date *(dd MMM yyyy)*	23 OCT 2020
End time *(00:00-23:59)*	8:30 (24 HR)
AE End Date and Time (derived)	23 OCT 2020 8:30
Severity	Grade 1/Mild ⬤
	Grade 2/Moderate ◯
	Grade 3/Severe ◯
	Grade 4 ◯
Is the adverse event serious?	Yes ◯
	No ⬤
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ◯
	No ◯
	Unknown ◯
Number of Days in ICU	

US3692001

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) **08 Apr 2021 14:22:33**

Generated On: 10 Jun 2021 09:24:06

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False

Relationship to investigational product	
Not Related	⬤
Related	◯
Not Applicable	◯

Relationship to Study Procedure	
Not Related	⬤
Related	◯
Not Applicable	◯

Action taken with investigational product	
None	⬤
Dose Delayed	◯
Investigational Product Withdrawn	◯
Not Applicable	◯

Other action taken (check all that apply)

None	True
Concomitant Medication	False
Concomitant Procedure	False

Outcome	
Fatal	◯
Not Recovered/Not Resolved	◯
Recovered/Resolved	⬤
Recovered/Resolved with Sequelae	◯
Recovering/Resolving	◯
Unknown	◯

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Ony)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3692001

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) **08 Apr 2021 14:22:33**

Generated On: 10 Jun 2021 09:24:06

AEID	USA-US123-2020-MRNA-1273-P30 1000004
Adverse event	BLEEDING GASTRIC ULCER

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)*	14 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)*	16 DEC 2020
End time *(00:00-23:59)*	
AE End Date and Time (derived)	

Severity　Grade 1/Mild ◯　Grade 2/Moderate ◯　Grade 3/Severe ⬤　Grade 4 ◯

Is the adverse event serious?　Yes ⬤　No ◯

AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date *(dd MMM yyyy)*	14 DEC 2020
Hospital Discharge Date *(dd MMM yyyy)*	16 DEC 2020

Admitted to ICU?　Yes ◯　No ⬤　Unknown ◯

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False

Relationship to investigational product

- Not Related ⬤
- Related ◯
- Not Applicable ◯

Relationship to Study Procedure

- Not Related ⬤
- Related ◯
- Not Applicable ◯

Action taken with investigational product

- None ◯
- Dose Delayed ◯
- Investigational Product Withdrawn ◯
- Not Applicable ⬤

Other action taken (check all that apply)

None	False
Concomitant Medication	True
Concomitant Procedure	True

Outcome

- Fatal ◯
- Not Recovered/Not Resolved ◯
- Recovered/Resolved ⬤
- Recovered/Resolved with Sequelae ◯
- Recovering/Resolving ◯
- Unknown ◯

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Narrative

PARTICIPANT PRESENTED TO ER WITH HEMATEMESIS ON 14DEC2020. AN EGD WAS CONDUCTED REVEALING A BLEEDING ULCER. NO CAUSE WAS IDENTIFIED. THE BLEEDING WAS STABILIZED AND THE PARTICIPANT WAS DISCHARGED ON 16DEC2020. CONCOMITANT MEDICATIONS AND PROCEDURES WILL BE UPDATED ONCE OSH RECORDS ARE RECEIVED. UPDATE: MR RECEIVED AND EDC UPDATED ACCORDINGLY. RESULT OF NEGATIVE WAS PROVIDED FOR A COVID-19 TEST, BUT THE SPECIMEN AND TEST TYPE WERE NOT PROVIDED.

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

FDA-CBER-2022-1614-3321824

US3692001

Folder: Adverse Events
Form: Adverse Events (5)
Data signed: (b) (4) **08 Apr 2021 14:22:33**
Generated On: 10 Jun 2021 09:24:06

AEID	
Adverse event	HEADACHE
Was this a medically-attended AE?	Yes ◯ No ⬤
Was this a Solicited Adverse Reaction?	Yes ◯ No ⬤
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ◯ No ⬤
Start date *(dd MMM yyyy)*	11 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)*	11 DEC 2020
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ⬤ Grade 2/Moderate ◯ Grade 3/Severe ◯ Grade 4 ◯
Is the adverse event serious?	Yes ◯ No ⬤

AE is serious due To (check all that apply)

Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ◯ No ◯ Unknown ◯
Number of Days in ICU	

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False

Relationship to investigational product	Not Related	●
	Related	○
	Not Applicable	○

Relationship to Study Procedure	Not Related	●
	Related	○
	Not Applicable	○

Action taken with investigational product	None	○
	Dose Delayed	○
	Investigational Product Withdrawn	○
	Not Applicable	●

Other action taken (check all that apply)

None	False
Concomitant Medication	True
Concomitant Procedure	False

Outcome	Fatal	○
	Not Recovered/Not Resolved	○
	Recovered/Resolved	●
	Recovered/Resolved with Sequelae	○
	Recovering/Resolving	○
	Unknown	○

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Ony)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3692001
Folder: Adverse Events
Form: Adverse Events (6)
Data signed: (b) (4) **08 Apr 2021 14:22:33**
Generated On: 10 Jun 2021 09:24:06

AEID	
Adverse event	EOSINOPHILIC ESOPHAGITIS
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)*	14 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)*	18 JAN 2021
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ◯
	Grade 2/Moderate ⬤
	Grade 3/Severe ◯
	Grade 4 ◯
Is the adverse event serious?	Yes ◯
	No ⬤
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ◯
	No ◯
	Unknown ◯
Number of Days in ICU	

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False

Relationship to investigational product	Not Related ⬤
	Related ◯
	Not Applicable ◯

Relationship to Study Procedure	Not Related ⬤
	Related ◯
	Not Applicable ◯

Action taken with investigational product	None ◯
	Dose Delayed ◯
	Investigational Product Withdrawn ◯
	Not Applicable ⬤

Other action taken (check all that apply)

None	False
Concomitant Medication	True
Concomitant Procedure	False

Outcome	Fatal ◯
	Not Recovered/Not Resolved ◯
	Recovered/Resolved ⬤
	Recovered/Resolved with Sequelae ◯
	Recovering/Resolving ◯
	Unknown ◯

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Ony)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) **08 Apr 2021 14:22:33**

Generated On: 10 Jun 2021 09:24:06

AEID	
Adverse event	TACHYPNEA
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)*	08 FEB 2021
Start time *(00:00-23:59)*	12:29 (24 HR)
AE start date and time (derived)	08 FEB 2021 12:29
Ongoing?	Yes ○ No ●
If not Ongoing, end date *(dd MMM yyyy)*	19 MAR 2021
End time *(00:00-23:59)*	09:32 (24 HR)
AE End Date and Time (derived)	19 MAR 2021 09:32
Severity	Grade 1/Mild ● Grade 2/Moderate ○ Grade 3/Severe ○ Grade 4 ○
Is the adverse event serious?	Yes ○ No ●
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ○ No ○ Unknown ○
Number of Days in ICU	

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False

Relationship to investigational product	Not Related ●
	Related ○
	Not Applicable ○

Relationship to Study Procedure	Not Related ●
	Related ○
	Not Applicable ○

Action taken with investigational product	None ●
	Dose Delayed ○
	Investigational Product Withdrawn ○
	Not Applicable ○

Other action taken (check all that apply)

None	True
Concomitant Medication	False
Concomitant Procedure	False

Outcome	Fatal ○
	Not Recovered/Not Resolved ○
	Recovered/Resolved ●
	Recovered/Resolved with Sequelae ○
	Recovering/Resolving ○
	Unknown ○

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Ony)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) **19 Feb 2021 23:32:08**

Generated On: 10 Jun 2021 09:24:06

Were any prior/concomitant medications and/or vaccinations taken?   Yes ⬤

                                                                            No ◯

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

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) **19 Feb 2021 23:32:08**

Generated On: 10 Jun 2021 09:24:06

Name of Medication	SIMVASTATIN
Prophylaxis	Yes ⚪
	No ⬤
Indication	HYPERLIPIDEMIA
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 ⚪

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) **19 Feb 2021 23:32:08**

Generated On: 10 Jun 2021 09:24:06

Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify

Start date *(dd MMM yyyy)* — UN UNK 2016

Start date completely unknown — False

Ongoing? — Yes ● / No ◯

If not Ongoing, End date *(dd MMM yyyy)*

Was this medication taken for solicited event? — Yes ◯ / No ●

Separate Dosage Number (derived) — 1

Interval Dosage Unit Number (derived) — 1

Interval Dosage Definition (derived) — 802 ◯ / 803 ◯ / 804 ●

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) **19 Feb 2021 23:32:08**

Generated On: 10 Jun 2021 09:24:06

Name of Medication	TESTOSTERONE CYPIONATE

Prophylaxis

Yes ◯

No ⬤

Indication	LOW TESTOSTERONE
Dose per administration	200

Dose unit

mg ⬤

ug ◯

mL ◯

g ◯

IU ◯

tablet ◯

capsule ◯

puff ◯

Other ◯

If dose unit is Other, specify

Frequency

once daily ◯

twice daily ◯

three times daily ◯

four times daily ◯

every other day ◯

every week ◯

every month ◯

as needed ◯

once ◯

unknown ◯

other ⬤

If frequency is Other, specify	EVERY TWO WEEKS

Route of administration

Oral ◯

Topical ◯

Subcutaneous ◯

Transdermal ◯

Intraocular ◯

Intramuscular	⬤
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 2016
Start date completely unknown	False
Ongoing?	Yes ⬤
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) **19 Feb 2021 23:32:08**

Generated On: 10 Jun 2021 09:24:06

Name of Medication	FLU VACCINE

Prophylaxis

Yes ●

No ○

Indication	PROPHYLAXIS FOR FLU
Dose per administration	.5

Dose unit

mg ○

ug ○

mL ●

g ○

IU ○

tablet ○

capsule ○

puff ○

Other ○

If dose unit is Other, specify _____

Frequency

once daily ○

twice daily ○

three times daily ○

four times daily ○

every other day ○

every week ○

every month ○

as needed ○

once ●

unknown ○

other ○

If frequency is Other, specify _____

Route of administration

Oral ○

Topical ○

Subcutaneous ○

Transdermal ○

Intraocular ○

Intramuscular	●
Respiratory (Inhalation)	○
Intralesional	○
Intraperiteoneal	○
Nasal	○
Vaginal	○
Rectal	○
Intravenous	○
Intravenous Bolus	○
Intravenous Drip	○
Other	○

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN NOV 2020
Start date completely unknown	False
Ongoing? Yes	○
No	●
If not Ongoing, End date *(dd MMM yyyy)*	UN NOV 2020
Was this medication taken for solicited event? Yes	○
No	●
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived) 802	○
803	○
804	○

Name of Medication	PANTOPRAZOLE

Prophylaxis

Yes ◯

No ⬤

Indication	GASTRIC ULCER/EOSINOPHILIC ESOPHAGITIS
Dose per administration	40

Dose unit

mg ⬤

ug ◯

mL ◯

g ◯

IU ◯

tablet ◯

capsule ◯

puff ◯

Other ◯

If dose unit is Other, specify

Frequency

once daily ◯

twice daily ⬤

three times daily ◯

four times daily ◯

every other day ◯

every week ◯

every month ◯

as needed ◯

once ◯

unknown ◯

other ◯

If frequency is Other, specify

Route of administration

Oral ⬤

Topical ◯

Subcutaneous ◯

Transdermal ◯

Intraocular	◯
Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	16 DEC 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	04 JAN 2021
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ⬤

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4)   **19 Feb 2021 23:32:08**

Generated On: 10 Jun 2021 09:24:06

Name of Medication	TUMS (CALCIUM CARBONATE)

Prophylaxis	
	Yes ○
	No ●

Indication	GERD
Dose per administration	750

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 ○

PRODUCTION RELEASE (v12.003
EAB) (1725)

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 2018
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	16 DEC 2020
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) **19 Feb 2021 23:32:08**

Generated On: 10 Jun 2021 09:24:06

Name of Medication	ASPIRIN

Prophylaxis	
	Yes ⚪
	No ⬤

Indication	HEADACHE
Dose per administration	81

Dose unit	
	mg ⬤
	ug ⚪
	mL ⚪
	g ⚪
	IU ⚪
	tablet ⚪
	capsule ⚪
	puff ⚪
	Other ⚪

If dose unit is Other, specify _____

Frequency	
	once daily ⚪
	twice daily ⚪
	three times daily ⚪
	four times daily ⚪
	every other day ⚪
	every week ⚪
	every month ⚪
	as needed ⚪
	once ⬤
	unknown ⚪
	other ⚪

If frequency is Other, specify _____

Route of administration	
	Oral ⬤
	Topical ⚪
	Subcutaneous ⚪
	Transdermal ⚪
	Intraocular ⚪

Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	11 DEC 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	11 DEC 2020
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

Name of Medication	SODIUM CHLORIDE

Prophylaxis	Yes ⚪
	No ⚫

Indication	GASTRIC ULCER

Dose per administration	100

Dose unit	mg ⚪
	ug ⚪
	mL ⚫
	g ⚪
	IU ⚪
	tablet ⚪
	capsule ⚪
	puff ⚪
	Other ⚪

If dose unit is Other, specify	

Frequency	once daily ⚪
	twice daily ⚪
	three times daily ⚪
	four times daily ⚪
	every other day ⚪
	every week ⚪
	every month ⚪
	as needed ⚪
	once ⚪
	unknown ⚪
	other ⚫

If frequency is Other, specify	PER HOUR

Route of administration	Oral ⚪
	Topical ⚪
	Subcutaneous ⚪
	Transdermal ⚪
	Intraocular ⚪

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Data signed: (b) (4) **19 Feb 2021 23:32:08**
Generated On: 10 Jun 2021 09:24:06

Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	⬤
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	14 DEC 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	15 DEC 2020
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ◯

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) **19 Feb 2021 23:32:08**

Generated On: 10 Jun 2021 09:24:06

Name of Medication	ZOFRAN
Prophylaxis	Yes ◯
	No ⬤

Indication	GASTRIC ULCER
Dose per administration	UNK
Dose unit	mg ◯
	ug ◯
	mL ◯
	g ◯
	IU ◯
	tablet ◯
	capsule ◯
	puff ◯
	Other ⬤
If dose unit is Other, specify	UNKNOWN DOSAGE
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 ◯

PRODUCTION RELEASE (v12.003
EAB) (1725)

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) **19 Feb 2021 23:32:08**

Generated On: 10 Jun 2021 09:24:06

Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	●
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify

Start date *(dd MMM yyyy)* 14 DEC 2020

Start date completely unknown False

Ongoing? Yes ◯ No ●

If not Ongoing, End date *(dd MMM yyyy)* 15 DEC 2020

Was this medication taken for solicited event? Yes ◯ No ●

Separate Dosage Number (derived)

Interval Dosage Unit Number (derived)

Interval Dosage Definition (derived) 802 ◯ 803 ◯ 804 ◯

FDA-CBER-2022-1614-3321847

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) **19 Feb 2021 23:32:08**

Generated On: 10 Jun 2021 09:24:06

Name of Medication	PRILOSEC (OMEPRAZOLE)

Prophylaxis
Yes ◯
No ⬤

Indication	GASTRIC ULCER
Dose per administration	40

Dose unit
mg ⬤
ug ◯
mL ◯
g ◯
IU ◯
tablet ◯
capsule ◯
puff ◯
Other ◯

If dose unit is Other, specify

Frequency
once daily ◯
twice daily ⬤
three times daily ◯
four times daily ◯
every other day ◯
every week ◯
every month ◯
as needed ◯
once ◯
unknown ◯
other ◯

If frequency is Other, specify

Route of administration
Oral ⬤
Topical ◯
Subcutaneous ◯
Transdermal ◯
Intraocular ◯

Intramuscular	◯
Respiratory (Inhalation)	◯
Intralesional	◯
Intraperiteoneal	◯
Nasal	◯
Vaginal	◯
Rectal	◯
Intravenous	◯
Intravenous Bolus	◯
Intravenous Drip	◯
Other	◯

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	16 DEC 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	18 JAN 2021
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ⬤

US3692001

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) **19 Feb 2021 23:32:08**

Generated On: 10 Jun 2021 09:24:06

Were any concomitant procedures performed?   Yes ●

                                                              No ◯

If yes, please complete Concomitant Procedures form.

US3692001

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) **19 Feb 2021 23:32:08**

Generated On: 10 Jun 2021 09:24:06

Procedure/Surgery date *(dd MMM yyyy)*	Procedure/Surgery	Indication	If indication is Other, specify
14 DEC 2020	ESOPHAGOGASTRODUODENOSC OPY (EGD)	Adverse Event	

US3692001

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:24:06

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 _____

Date of study discontinuation/completion *(dd MMM yyyy)*	

Reason for discontinuation	
AE (specify)	◯
SAE (specify)	◯
Complete	◯
Death	◯
Lost To Follow-up	◯
Physician decision (specify)	◯
Pregnancy	◯
Protocol deviation (specify)	◯
Study Terminated By Sponsor	◯
Withdrawal of consent by participant (specify)	◯
Other	◯

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify	

If reason for discontinuation is Death, main cause of death	
Adverse event	◯
Unknown	◯
Other	◯

If main cause of death is Other, specify	
Date of death *(dd MMM yyyy)*	

Was autopsy performed?	
Yes	◯
No	◯
Unknown	◯

SAEID	USA-US123-2020-MRNA-1273-P30 1000004
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	GAY
Site Address: Street	130 MASON FARM RD, CB #7030
Site Address: City	CHAPEL HILL
Site Address: State	
Site Address: Postal Code	27599-7030
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

SAEID	USA-US123-2020-MRNA-1273-P30 1000004
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	GAY
Site Address: Street	130 MASON FARM RD, CB #7030
Site Address: City	CHAPEL HILL
Site Address: State	
Site Address: Postal Code	27599-7030
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	21/DEC/2020 12:46
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

US3692001
Folder: SAE USA-US123-2020-MRNA-1273-P301000004
Form: Safety Report Form (2)
Data signed: (b) (4) **19 Feb 2021 23:32:08**
Generated On: 10 Jun 2021 09:24:06

SAEID	USA-US123-2020-MRNA-1273-P30 1000004
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	GAY
Site Address: Street	130 MASON FARM RD, CB #7030
Site Address: City	CHAPEL HILL
Site Address: State	
Site Address: Postal Code	27599-7030
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	22/DEC/2020 09:28
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

Folder: SAE USA-US123-2020-MRNA-1273-P301000004
Form: Safety Report Form (3)
Data signed: (b) (4) **19 Feb 2021 23:32:08**
Generated On: 10 Jun 2021 09:24:06

SAEID	USA-US123-2020-MRNA-1273-P30 1000004
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	GAY
Site Address: Street	130 MASON FARM RD, CB #7030
Site Address: City	CHAPEL HILL
Site Address: State	
Site Address: Postal Code	27599-7030
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	28/DEC/2020 22:03
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

Audit

US3692001 (Prod: University of North Carolina at Chapel Hill)

US3692001

Form: Participant Creation

Generated On: 10 Jun 2021 09:24:06

Participant ID

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'US3692001'	RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 18:14:54

US3692001
Folder: Screening
Form: Visit Date
Generated On: 10 Jun 2021 09:24:06
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered 'Yes (Y)'	Yaa Ofori-Marfoh (b) (4) (b) (4)	27 Aug 2020 18:30:37

US3692001

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:24:06

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered '25 Aug 2020' reason for change: Data Entry Error	Yaa Ofori-Marfoh (b) (4) (b) (4)	28 Aug 2020 12:49:30
User entered '26 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 18:14:56

US3692001
Folder: Screening
Form: Visit Date
Generated On: 10 Jun 2021 09:24:06

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	01 Apr 2021 21:15:33
Signature has been broken.	Maria Stetson (b) (4) (b) (4)	31 Mar 2021 12:34:51
User entered 'Home (Home)' reason for change: New Information	Maria Stetson (b) (4) (b) (4)	31 Mar 2021 12:34:51
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered 'Clinic (Clinic)' reason for change: Data Entry Error	Yaa Ofori-Marfoh (b) (4) (b) (4)	28 Aug 2020 12:49:35
User entered 'Home (Home)' reason for change: Data Entry Error	Yaa Ofori-Marfoh (b) (4) (b) (4)	28 Aug 2020 12:49:30
User entered 'Clinic (Clinic)'	Yaa Ofori-Marfoh (b) (4) (b) (4)	27 Aug 2020 18:30:37

US3692001
Folder: Screening
Form: Visit Date
Generated On: 10 Jun 2021 09:24:06
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User entered 'SCRN'	System	27 Aug 2020 18:30:37

US3692001

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:24:06

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered (b) (6) 1963'	RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 18:14:57

US3692001
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:24:06

Age

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered '56'	Yaa Ofori-Marfoh (b) (4) (b) (4)	27 Aug 2020 18:50:05

US3692001
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:24:06
Age Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User entered 'YEARS'	System	27 Aug 2020 18:50:05

US3692001

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:24:06

Age (Derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User entered '56'	System	26 Aug 2020 21:36:26

US3692001
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:24:06
Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered 'Male (M)'	Yaa Ofori-Marfoh (b) (4) (b) (4)	27 Aug 2020 18:50:05

US3692001
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:24:06
Ethnicity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Yaa Ofori-Marfoh (b) (4) (b) (4)	27 Aug 2020 18:50:05

US3692001
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:24:06
White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered '1'	Yaa Ofori-Marfoh (b) (4) (b) (4)	27 Aug 2020 18:50:05

US3692001
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:24:06
Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered '0'	Yaa Ofori-Marfoh (b) (4) (b) (4)	27 Aug 2020 18:50:05

US3692001
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:24:06
Asian

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered '0'	Yaa Ofori-Marfoh (b) (4) (b) (4)	27 Aug 2020 18:50:05

US3692001
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:24:06

American Indian or Alaska Native

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered '0'	Yaa Ofori-Marfoh (b) (4) (b) (4)	27 Aug 2020 18:50:05

Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:24:06

Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered '0'	Yaa Ofori-Marfoh (b) (4) (b) (4)	27 Aug 2020 18:50:05

US3692001

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:24:06

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered '0'	Yaa Ofori-Marfoh (b) (4) (b) (4)	27 Aug 2020 18:50:05

US3692001
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:24:06
If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered empty.	Yaa Ofori-Marfoh (b) (4) (b) (4)	27 Aug 2020 18:50:05

US3692001
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:24:06
Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered '0'	Yaa Ofori-Marfoh (b) (4) (b) (4)	27 Aug 2020 18:50:05

US3692001
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:24:06
Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered '0'	Yaa Ofori-Marfoh (b) (4) (b) (4)	27 Aug 2020 18:50:05

US3692001
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 09:24:06
Date of Informed Consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered '25 Aug 2020'	Becky Straub (b) (4)	26 Aug 2020 21:36:26

US3692001
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 09:24:06

Month and Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User entered 'Aug 2020'	System	26 Aug 2020 21:36:26

Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User entered '2020'	System	26 Aug 2020 21:36:26

US3692001
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 09:24:06
Protocol Version

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered 'Amendment 3 (3)'	Becky Straub (b) (4)	26 Aug 2020 21:36:26

US3692001
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 09:24:06
Was participant enrolled in the study?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered 'Yes (Y)'	Becky Straub (b) (4)	26 Aug 2020 21:36:26

US3692001
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 09:24:06
If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered empty.	Becky Straub (b) (4)	26 Aug 2020 21:36:26

US3692001
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 09:24:06
If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered empty.	Becky Straub (b) (4)	26 Aug 2020 21:36:26

US3692001
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 09:24:06
Was this participant screened previously?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered 'No (N)'	Becky Straub (b) (4)	26 Aug 2020 21:36:26

US3692001
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 09:24:06
If Yes, previous participant number

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 18:14:56

US3692001
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 09:24:06
Enrollment Trigger

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User entered '1'	System	26 Aug 2020 21:36:26

US3692001

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:24:06

Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered 'Yes (Y)'	Becky Straub (b) (4)	26 Aug 2020 21:31:05

US3692001

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 09:24:06

Were any significant conditions reported?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered 'Yes (Y)'	Yaa Ofori-Marfoh (b) (4) (b) (4)	28 Aug 2020 15:15:16

US3692001

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:24:06

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 15:20:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 15:20:37
Data point term sent to Coder	System	28 Aug 2020 15:19:47
User entered 'Hyperlipidemia'	Yaa Ofori-Marfoh (b) (4) (b) (4)	28 Aug 2020 15:19:04

US3692001
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 09:24:06
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered 'UN UNK 2016'	Yaa Ofori-Marfoh (b) (4) (b) (4)	28 Aug 2020 15:19:04

US3692001

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:24:06

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered '0'	Yaa Ofori-Marfoh (b) (4) (b) (4)	28 Aug 2020 15:19:04

US3692001

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:24:06

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Sep 2020 20:45:29
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Sep 2020 20:45:29
User entered 'Yes (Y)' reason for change: Per Query Resolution	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 20:45:29
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Aug 2020 15:19:04
User entered empty.	Yaa Ofori-Marfoh (b) (4) (b) (4)	28 Aug 2020 15:19:04

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered empty.	Yaa Ofori-Marfoh (b) (4) (b) (4)	28 Aug 2020 15:19:04

US3692001

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:24:06

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered '0'	Yaa Ofori-Marfoh (b) (4) (b) (4)	28 Aug 2020 15:19:04

US3692001
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 09:24:06
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User entered 'Jan 2016'	System	28 Aug 2020 15:19:04

US3692001
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 09:24:06
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User entered '2016'	System	28 Aug 2020 15:19:04

US3692001

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:24:06

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User entered empty.	System	28 Aug 2020 15:19:04

US3692001
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 09:24:06

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User entered empty.	System	28 Aug 2020 15:19:04

US3692001

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:24:06

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User coded data point as SOC: Investigations, HLGT: Endocrine investigations (incl sex hormones), HLT: Reproductive hormone analyses, PT: Blood testosterone decreased, LLT: Testosterone low - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 15:21:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 15:21:40
Data point term sent to Coder	System	28 Aug 2020 15:20:52
User entered 'Low testosterone'	Yaa Ofori-Marfoh (b) (4) (b) (4)	28 Aug 2020 15:19:51

US3692001
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 09:24:06
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered 'UN UNK 2015'	Yaa Ofori-Marfoh (b) (4) (b) (4)	28 Aug 2020 15:19:51

US3692001

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:24:06

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered '0'	Yaa Ofori-Marfoh (b) (4) (b) (4)	28 Aug 2020 15:19:51

US3692001

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:24:06

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Sep 2020 20:45:44
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Sep 2020 20:45:44
User entered 'Yes (Y)' reason for change: Per Query Resolution	Abigail Riddick (b) (4) (b) (4)	01 Sep 2020 20:45:44
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Aug 2020 15:19:51
User entered empty.	Yaa Ofori-Marfoh (b) (4) (b) (4)	28 Aug 2020 15:19:51

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:24:06

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered empty.	Yaa Ofori-Marfoh (b) (4) (b) (4)	28 Aug 2020 15:19:51

Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 09:24:06

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered '0'	Yaa Ofori-Marfoh (b) (4) (b) (4)	28 Aug 2020 15:19:51

US3692001
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 09:24:06

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User entered 'Jan 2015'	System	28 Aug 2020 15:19:51

US3692001

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:24:06

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User entered '2015'	System	28 Aug 2020 15:19:51

US3692001

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:24:06

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User entered empty.	System	28 Aug 2020 15:19:51

US3692001
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 09:24:06

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User entered empty.	System	28 Aug 2020 15:19:51

US3692001
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 09:24:06
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastrooesophageal reflux disease, LLT: GERD - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Dec 2020 21:14:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Dec 2020 21:14:50
Data point term sent to Coder	System	21 Dec 2020 21:14:12
User entered 'GERD (Gastroesophageal reflux disease)'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:13:26

US3692001
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 09:24:06
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered 'UN Jan 2018'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:13:26

Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 09:24:06
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered '0'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:13:26

US3692001
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 09:24:06
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered 'Yes (Y)'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:13:26

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered empty.	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:13:26

US3692001

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:24:06

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered '0'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:13:26

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User entered 'Jan 2018'	System	21 Dec 2020 21:13:26

US3692001
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 09:24:06
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User entered '2018'	System	21 Dec 2020 21:13:26

US3692001
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 09:24:06

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User entered empty.	System	21 Dec 2020 21:13:26

US3692001
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 09:24:06
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User entered empty.	System	21 Dec 2020 21:13:26

US3692001

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:06

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered 'Yes (Y)' reason for change: Data Entry Error	Abigail Riddick (b) (4) (b) (4)	31 Aug 2020 18:10:22
User closed query 'Response to were vital signs assessed is No, but data is provided below. Please correct.' (Site from System).	System	28 Aug 2020 12:58:35
User opened query 'Response to were vital signs assessed is No, but data is provided below. Please correct.' (Site from System).	System	28 Aug 2020 12:58:12
User entered 'No (N)' reason for change: Data Entry Error	Yaa Ofori-Marfoh (b) (4) (b) (4)	28 Aug 2020 12:58:12
User entered 'Yes (Y)'	Yaa Ofori-Marfoh (b) (4) (b) (4)	27 Aug 2020 20:49:38

US3692001
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:06

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:45:25
User closed query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	01 Sep 2020 17:19:59
User entered '26 Aug 2020' reason for change: Data Entry Error	Abigail Riddick (b) (4) (b) (4)	31 Aug 2020 18:10:22
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	28 Aug 2020 12:58:45
User entered empty; reason for change Data Entry Error	Yaa Ofori-Marfoh (b) (4) (b) (4)	28 Aug 2020 12:58:45
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	28 Aug 2020 12:58:35
User entered ' Aug ' (non-conformant).	Yaa Ofori-Marfoh (b) (4) (b) (4)	28 Aug 2020 12:58:35
Query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' answered with 'Vital signs were not completed on date of Screening. In-person assessments were completed on date of randomization because the in-person screening and Day 1 assessments were combined as allowed per protocol' (Site from System).	Yaa Ofori-Marfoh (b) (4) (b) (4)	28 Aug 2020 12:57:50
User opened query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	28 Aug 2020 12:49:30
User entered '26 Aug 2020'	Yaa Ofori-Marfoh (b) (4) (b) (4)	27 Aug 2020 20:49:38

US3692001
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:06

Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	01 Sep 2020 17:20:05
User entered '12:15' reason for change: Data Entry Error	Abigail Riddick (b) (4) (b) (4)	31 Aug 2020 18:10:22
Query 'Data is required. Please provide.' answered with 'Not required at screening per protocol.' (Site from System).	Yaa Ofori-Marfoh (b) (4) (b) (4)	27 Aug 2020 20:50:51
User opened query 'Data is required. Please provide.' (Site from System).	System	27 Aug 2020 20:49:38
User entered empty.	Yaa Ofori-Marfoh (b) (4) (b) (4)	27 Aug 2020 20:49:38

Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:06

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User entered '26 Aug 2020 12:15'	System	31 Aug 2020 18:10:22
User entered empty.	System	27 Aug 2020 20:49:38

US3692001
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:06

Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered '175.2' cm reason for change: Data Entry Error	Abigail Riddick (b) (4) (b) (4)	31 Aug 2020 18:10:22
User closed query 'Data is required. Please provide.' (Site from System).	System	28 Aug 2020 12:58:12
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	28 Aug 2020 12:58:12
User opened query 'Data is required. Please provide.' (Site from System).	System	28 Aug 2020 12:58:02
User entered empty; reason for change Data Entry Error	Yaa Ofori-Marfoh (b) (4) (b) (4)	28 Aug 2020 12:58:02
User entered '175.2' cm	Yaa Ofori-Marfoh (b) (4) (b) (4)	27 Aug 2020 20:49:38
DataPoint set to visible.	System	26 Aug 2020 21:36:26

US3692001

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:06

Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered '75.0' kg reason for change: Data Entry Error	Abigail Riddick (b) (4) (b) (4)	31 Aug 2020 18:10:22
User closed query 'Data is required. Please provide.' (Site from System).	System	28 Aug 2020 12:58:12
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	28 Aug 2020 12:58:12
User opened query 'Data is required. Please provide.' (Site from System).	System	28 Aug 2020 12:58:02
User entered empty; reason for change Data Entry Error	Yaa Ofori-Marfoh (b) (4) (b) (4)	28 Aug 2020 12:58:02
User entered '75.0' kg	Yaa Ofori-Marfoh (b) (4) (b) (4)	27 Aug 2020 20:49:38
DataPoint set to visible.	System	26 Aug 2020 21:36:26

US3692001
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:06
BMI *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User entered '24.43392'	System	31 Aug 2020 18:10:22
User entered empty.	System	28 Aug 2020 12:58:02
User entered '24.4'	System	27 Aug 2020 20:49:38
DataPoint set to visible.	System	26 Aug 2020 21:36:26

US3692001
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:06
BMI units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User entered 'kg/m2'	System	31 Aug 2020 18:10:22
User entered empty.	System	28 Aug 2020 12:58:02
User entered 'kg/m2'	System	27 Aug 2020 20:49:38
DataPoint set to visible.	System	26 Aug 2020 21:36:26

US3692001
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:06
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User closed query 'Per CDM: It has been noted that Screening Vital Signs and Visit Day1 Vital Signs have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 08:43:19
Query 'Per CDM: It has been noted that Screening Vital Signs and Visit Day1 Vital Signs have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly.' answered with 'Updated. ' (Site from DM).	Mandy Tipton (b) (4) (b) (4)	09 Sep 2020 21:19:42
User entered missing code ND - Not Done; reason for change Data Entry Error	Mandy Tipton (b) (4) (b) (4)	09 Sep 2020 21:19:34
User opened query 'Per CDM: It has been noted that Screening Vital Signs and Visit Day1 Vital Signs have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 18:13:40
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	01 Sep 2020 17:20:08
User entered '36.8' C reason for change: Data Entry Error	Abigail Riddick (b) (4) (b) (4)	31 Aug 2020 18:10:22
Query 'Data is required. Please provide.' answered with 'Not required at screening per protocol.' (Site from System).	Yaa Ofori-Marfoh (b) (4) (b) (4)	27 Aug 2020 20:50:57
User opened query 'Data is required. Please provide.' (Site from System).	System	27 Aug 2020 20:49:38

US3692001
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:06
Temperature *(xxx.x)*

Audit	User	Time (GMT)
User entered empty.	Yaa Ofori-Marfoh (b) (4) (b) (4)	27 Aug 2020 20:49:38

US3692001

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:06

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered empty; reason for change Data Entry Error	Mandy Tipton (b) (4) (b) (4)	09 Sep 2020 21:19:34
User entered 'Oral (Oral)' reason for change: Data Entry Error	Abigail Riddick (b) (4) (b) (4)	31 Aug 2020 18:10:22
User entered empty.	Yaa Ofori-Marfoh (b) (4) (b) (4)	27 Aug 2020 20:49:38

US3692001
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:06
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered empty.	Yaa Ofori-Marfoh (b) (4) (b) (4)	27 Aug 2020 20:49:38

US3692001
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:06

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered missing code ND - Not Done; reason for change Data Entry Error	Mandy Tipton (b) (4) (b) (4)	09 Sep 2020 21:19:34
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	01 Sep 2020 17:20:12
User entered '70' reason for change: Data Entry Error	Abigail Riddick (b) (4) (b) (4)	31 Aug 2020 18:10:22
Query 'Data is required. Please provide.' answered with 'Not required at screening per protocol.' (Site from System).	Yaa Ofori-Marfoh (b) (4) (b) (4)	27 Aug 2020 20:51:01
User opened query 'Data is required. Please provide.' (Site from System).	System	27 Aug 2020 20:49:38
User entered empty.	Yaa Ofori-Marfoh (b) (4) (b) (4)	27 Aug 2020 20:49:38

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User entered 'bpm'	System	31 Aug 2020 18:10:22
User entered empty.	System	27 Aug 2020 20:49:38

FDA-CBER-2022-1614-3321934

US3692001
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:06
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered missing code ND - Not Done; reason for change Data Entry Error	Mandy Tipton (b) (4) (b) (4)	09 Sep 2020 21:19:34
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	01 Sep 2020 17:20:20
User entered '18' reason for change: Data Entry Error	Abigail Riddick (b) (4) (b) (4)	31 Aug 2020 18:10:22
Query 'Data is required. Please provide.' answered with 'Not required at screening per protocol.' (Site from System).	Yaa Ofori-Marfoh (b) (4) (b) (4)	27 Aug 2020 20:51:06
User opened query 'Data is required. Please provide.' (Site from System).	System	27 Aug 2020 20:49:38
User entered empty.	Yaa Ofori-Marfoh (b) (4) (b) (4)	27 Aug 2020 20:49:38

US3692001
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:06
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User entered 'breaths/min'	System	31 Aug 2020 18:10:22
User entered empty.	System	27 Aug 2020 20:49:38

US3692001
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:06

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered missing code ND - Not Done; reason for change Data Entry Error	Mandy Tipton (b) (4) (b) (4)	09 Sep 2020 21:19:34
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	01 Sep 2020 17:20:22
User entered '117' reason for change: Data Entry Error	Abigail Riddick (b) (4) (b) (4)	31 Aug 2020 18:10:22
Query 'Data is required. Please provide.' answered with 'Not required at screening per protocol.' (Site from System).	Yaa Ofori-Marfoh (b) (4) (b) (4)	27 Aug 2020 20:51:10
User opened query 'Data is required. Please provide.' (Site from System).	System	27 Aug 2020 20:49:38
User entered empty.	Yaa Ofori-Marfoh (b) (4) (b) (4)	27 Aug 2020 20:49:38

US3692001
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:06
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User entered 'mmHg'	System	31 Aug 2020 18:10:22
User entered empty.	System	27 Aug 2020 20:49:38

US3692001
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:06
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered missing code ND - Not Done; reason for change Data Entry Error	Mandy Tipton (b) (4) (b) (4)	09 Sep 2020 21:19:34
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	01 Sep 2020 17:20:27
User entered '71' reason for change: Data Entry Error	Abigail Riddick (b) (4) (b) (4)	31 Aug 2020 18:10:22
Query 'Data is required. Please provide.' answered with 'Not required at screening per protocol.' (Site from System).	Yaa Ofori-Marfoh (b) (4) (b) (4)	27 Aug 2020 20:51:13
User opened query 'Data is required. Please provide.' (Site from System).	System	27 Aug 2020 20:49:38
User entered empty.	Yaa Ofori-Marfoh (b) (4) (b) (4)	27 Aug 2020 20:49:38

US3692001
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:06

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User entered 'mmHg'	System	31 Aug 2020 18:10:22
User entered empty.	System	27 Aug 2020 20:49:38

US3692001
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:06
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46

US3692001
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:06
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46

Folder: Screening
Form: Physical Examination
Generated On: 10 Jun 2021 09:24:06

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered 'No (N)'	Yaa Ofori-Marfoh (b) (4) (b) (4)	28 Aug 2020 12:58:56

US3692001

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:24:06

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered empty.	Yaa Ofori-Marfoh (b) (4) (b) (4)	28 Aug 2020 12:58:56

US3692001
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:24:06
Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered 'No (N)'	Yaa Ofori-Marfoh (b) (4) (b) (4)	28 Aug 2020 15:04:58

Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:24:06

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered 'No (N)'	Yaa Ofori-Marfoh (b) (4) (b) (4)	28 Aug 2020 15:04:58

US3692001

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:24:06

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)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered 'No (N)'	Yaa Ofori-Marfoh (b) (4) (b) (4)	28 Aug 2020 15:04:58

US3692001

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:24:06

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)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered 'No (N)'	Yaa Ofori-Marfoh (b) (4) (b) (4)	28 Aug 2020 15:04:58

US3692001
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:24:06
Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered 'No (N)'	Yaa Ofori-Marfoh (b) (4) (b) (4)	28 Aug 2020 15:04:58

US3692001

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:24:06

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)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered 'No (N)'	Yaa Ofori-Marfoh (b) (4) (b) (4)	28 Aug 2020 15:04:58

US3692001

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:24:06

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)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered 'No (N)'	Yaa Ofori-Marfoh (b) (4) (b) (4)	28 Aug 2020 15:04:58

US3692001

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:24:06

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)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered 'No (N)'	Yaa Ofori-Marfoh (b) (4) (b) (4)	28 Aug 2020 15:04:58

US3692001

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:24:06

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)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered 'No (N)'	Yaa Ofori-Marfoh (b) (4) (b) (4)	28 Aug 2020 15:04:58

US3692001

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:24:06

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)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered 'No (N)'	Yaa Ofori-Marfoh (b) (4) (b) (4)	28 Aug 2020 15:04:58

US3692001

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:24:06

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)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered 'No (N)'	Yaa Ofori-Marfoh (b) (4) (b) (4)	28 Aug 2020 15:04:58

US3692001
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:24:06
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered 'Yes (Y)'	Yaa Ofori-Marfoh (b) (4) (b) (4)	28 Aug 2020 15:04:58

US3692001

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:24:06

Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered 'WORKS IN AN OFFICE; 13 OTHERS MOSTLY MASKED. PATIENT LAWYER - FACE TO FACE INTERACTION & CLIENTS 1-2 PEOPLE/DAY MIN, NOT ALWAYS MASKED. FREQUENT TRAVELING TO BUSINESSES/FACILITIES. Ex next week boston' reason for change: New Information	Yaa Ofori-Marfoh (b) (4) (b) (4)	28 Aug 2020 15:13:11
User entered 'Works in an office; 13 others mostly masked. Patient lawyer - face to face interaction & clients 1-2 people/day at minimum, not always masked. Frequent traveling to businesses/facilities. Ex - boston'	Yaa Ofori-Marfoh (b) (4) (b) (4)	28 Aug 2020 15:04:58

US3692001

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:24:06

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User closed query ''No Risk Identified' is not checked, however no other risks are selected. Please review and reconcile.' (Site from System).	System	28 Aug 2020 15:13:11
User opened query ''No Risk Identified' is not checked, however no other risks are selected. Please review and reconcile.' (Site from System).	System	28 Aug 2020 15:04:58
User entered '0'	Yaa Ofori-Marfoh (b) (4) (b) (4)	28 Aug 2020 15:04:58

US3692001

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:24:06

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered '0'	Yaa Ofori-Marfoh (b) (4) (b) (4)	28 Aug 2020 15:04:58

US3692001

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:24:06

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)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered '0'	Yaa Ofori-Marfoh (b) (4) (b) (4)	28 Aug 2020 15:04:58

US3692001

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:24:06

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)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered '0'	Yaa Ofori-Marfoh (b) (4) (b) (4)	28 Aug 2020 15:04:58

US3692001

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:24:06

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)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered '0'	Yaa Ofori-Marfoh (b) (4) (b) (4)	28 Aug 2020 15:04:58

US3692001

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:24:06

Resides in a single family home (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered '1' reason for change: New Information	Yaa Ofori-Marfoh (b) (4) (b) (4)	28 Aug 2020 15:13:11
User entered '0'	Yaa Ofori-Marfoh (b) (4) (b) (4)	28 Aug 2020 15:04:58

US3692001
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:24:06
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered '0'	Yaa Ofori-Marfoh (b) (4) (b) (4)	28 Aug 2020 15:04:58

US3692001
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:24:06
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered empty.	Yaa Ofori-Marfoh (b) (4) (b) (4)	28 Aug 2020 15:04:58

US3692001

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:24:06

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered 'Yes (Y)'	Becky Straub (b) (4)	26 Aug 2020 21:31:40

US3692001
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 10 Jun 2021 09:24:06

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered '26 Aug 2020'	Becky Straub (b) (4)	26 Aug 2020 21:31:40

US3692001
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 10 Jun 2021 09:24:06

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered 'Clinic (Clinic)'	Becky Straub (b) (4)	26 Aug 2020 21:31:40

US3692001
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 10 Jun 2021 09:24:06
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User entered 'VISIT1'	System	26 Aug 2020 21:31:40

US3692001
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 09:24:06

What was the date of randomization? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:45:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:24:57
User entered '26 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 18:20:20

US3692001

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:24:06

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered '108791'	RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 18:20:20

US3692001
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 09:24:06

In what Cohort was the participant enrolled?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 18:20:20

US3692001

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:24:06

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Aug 2020 21:33:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Aug 2020 21:33:43
User entered 'No (N)' reason for change: Data Entry Error	Becky Straub (b) (4)	26 Aug 2020 21:33:43
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Aug 2020 21:33:23
User entered empty.	Becky Straub (b) (4)	26 Aug 2020 21:33:23

US3692001

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:24:06

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Aug 2020 21:33:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Aug 2020 21:33:43
User entered 'No (N)' reason for change: Data Entry Error	Becky Straub (b) (4)	26 Aug 2020 21:33:43
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Aug 2020 21:33:23
User entered empty.	Becky Straub (b) (4)	26 Aug 2020 21:33:23

US3692001

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:24:06

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Aug 2020 21:33:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Aug 2020 21:33:43
User entered 'No (N)' reason for change: Data Entry Error	Becky Straub (b) (4)	26 Aug 2020 21:33:43
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Aug 2020 21:33:23
User entered empty.	Becky Straub (b) (4)	26 Aug 2020 21:33:23

US3692001

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:24:06

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Aug 2020 21:33:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Aug 2020 21:33:43
User entered 'No (N)' reason for change: Data Entry Error	Becky Straub (b) (4)	26 Aug 2020 21:33:43
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Aug 2020 21:33:23
User entered empty.	Becky Straub (b) (4)	26 Aug 2020 21:33:23

US3692001

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:24:06

Liver Disease

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Aug 2020 21:33:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Aug 2020 21:33:43
User entered 'No (N)' reason for change: Data Entry Error	Becky Straub (b) (4)	26 Aug 2020 21:33:43
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Aug 2020 21:33:23
User entered empty.	Becky Straub (b) (4)	26 Aug 2020 21:33:23

US3692001

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:24:06

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Nov 2020 13:41:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Nov 2020 13:41:48
User entered 'No (N)' reason for change: Data Entry Error	Kristi Kirkland (b) (4) (b) (4)	14 Nov 2020 13:41:48
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 18:22:57
User entered empty.	Erin Cardot (b) (4) (b) (4)	09 Nov 2020 18:22:57
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 08:05:57
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:05:56

US3692001
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 09:24:06
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User closed query 'Per CDM: It has been noted that Screening Vital Signs and Visit Day1 Vital Signs have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 11:49:40
Query 'Per CDM: It has been noted that Screening Vital Signs and Visit Day1 Vital Signs have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' answered with 'Updated. ' (Site from DM).	Mandy Tipton (b) (4) (b) (4)	09 Sep 2020 21:20:12
User entered missing code ND - Not Done; reason for change Data Entry Error	Mandy Tipton (b) (4) (b) (4)	09 Sep 2020 21:20:06
User opened query 'Per CDM: It has been noted that Screening Vital Signs and Visit Day1 Vital Signs have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 18:14:02
User entered '175.2' cm	Yaa Ofori-Marfoh (b) (4) (b) (4)	28 Aug 2020 15:28:25

US3692001
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 09:24:06
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered missing code ND - Not Done; reason for change Data Entry Error	Mandy Tipton (b) (4) (b) (4)	09 Sep 2020 21:20:06
User entered '75' kg	Yaa Ofori-Marfoh (b) (4) (b) (4)	28 Aug 2020 15:28:25

US3692001
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 09:24:06
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User closed query 'Per CDM: It has been noted that Screening Vital Signs and Visit Day1 Vital Signs have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 11:49:40
Query 'Per CDM: It has been noted that Screening Vital Signs and Visit Day1 Vital Signs have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' answered with 'Updated. ' (Site from DM).	Mandy Tipton (b) (4) (b) (4)	09 Sep 2020 21:20:12
User entered missing code ND - Not Done; reason for change Data Entry Error	Mandy Tipton (b) (4) (b) (4)	09 Sep 2020 21:20:06
User opened query 'Per CDM: It has been noted that Screening Vital Signs and Visit Day1 Vital Signs have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 18:14:02
User entered '175.2' cm	Yaa Ofori-Marfoh (b) (4) (b) (4)	28 Aug 2020 15:28:25

US3692001

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:24:06

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered missing code ND - Not Done; reason for change Data Entry Error	Mandy Tipton (b) (4) (b) (4)	09 Sep 2020 21:20:06
User entered '75' kg	Yaa Ofori-Marfoh (b) (4) (b) (4)	28 Aug 2020 15:28:25

US3692001

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:06

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User accepted default value 'Pre-Dose (PREDOSE)'	Yaa Ofori-Marfoh (b) (4) (b) (4)	28 Aug 2020 15:28:25

US3692001

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:06

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered 'Yes (Y)'	Yaa Ofori-Marfoh (b) (4) (b) (4)	28 Aug 2020 15:28:25

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered '26 Aug 2020'	Yaa Ofori-Marfoh (b) (4) (b) (4)	28 Aug 2020 15:28:25

FDA-CBER-2022-1614-3321985

US3692001

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:06

Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User closed query 'Data is required. Please provide.' (Site from System).	System	31 Aug 2020 18:10:58
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	31 Aug 2020 18:10:58
User entered '12:15' reason for change: Data Entry Error	Abigail Riddick (b) (4) (b) (4)	31 Aug 2020 18:10:58
User opened query 'Data is required. Please provide.' (Site from System).	System	28 Aug 2020 15:28:25
User entered empty.	Yaa Ofori-Marfoh (b) (4) (b) (4)	28 Aug 2020 15:28:25

US3692001

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:06

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User entered '26 Aug 2020 12:15'	System	31 Aug 2020 18:10:58
User entered empty.	System	28 Aug 2020 15:28:25

US3692001

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:06

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered '36.8' C	Yaa Ofori-Marfoh (b) (4) (b) (4)	28 Aug 2020 15:28:25

US3692001

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:06

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User closed query 'Data is required. Please provide.' (Site from System).	System	31 Aug 2020 18:11:11
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	31 Aug 2020 18:11:11
User entered 'Oral (Oral)' reason for change: Data Entry Error	Abigail Riddick (b) (4) (b) (4)	31 Aug 2020 18:11:11
User opened query 'Data is required. Please provide.' (Site from System).	System	28 Aug 2020 15:28:25
User entered empty.	Yaa Ofori-Marfoh (b) (4) (b) (4)	28 Aug 2020 15:28:25

US3692001
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:24:06
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered empty.	Yaa Ofori-Marfoh (b) (4) (b) (4)	28 Aug 2020 15:28:25

US3692001

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:06

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered '70'	Yaa Ofori-Marfoh (b) (4) (b) (4)	28 Aug 2020 15:28:25

US3692001
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:24:06
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User entered 'bpm'	System	28 Aug 2020 15:28:25

US3692001

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:06

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered '18'	Yaa Ofori-Marfoh (b) (4) (b) (4)	28 Aug 2020 15:28:25

US3692001

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:06

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User entered 'breaths/min'	System	28 Aug 2020 15:28:25

US3692001

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:06

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered '117'	Yaa Ofori-Marfoh (b) (4) (b) (4)	28 Aug 2020 15:28:25

US3692001

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:06

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User entered 'mmHg'	System	28 Aug 2020 15:28:25

US3692001

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:06

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered '71' reason for change: Data Entry Error	Abigail Riddick (b) (4) (b) (4)	31 Aug 2020 18:11:58
User entered '74'	Yaa Ofori-Marfoh (b) (4) (b) (4)	28 Aug 2020 15:28:25

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User entered 'mmHg'	System	28 Aug 2020 15:28:25

FDA-CBER-2022-1614-3321998

US3692001
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 09:24:06
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User closed query 'Per CDM: It has been noted that Screening Vital Signs and Visit Day1 Vital Signs have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 11:49:40
Query 'Per CDM: It has been noted that Screening Vital Signs and Visit Day1 Vital Signs have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' answered with 'Updated. ' (Site from DM).	Mandy Tipton (b) (4) (b) (4)	09 Sep 2020 21:20:12
User entered missing code ND - Not Done; reason for change Data Entry Error	Mandy Tipton (b) (4) (b) (4)	09 Sep 2020 21:20:06
User opened query 'Per CDM: It has been noted that Screening Vital Signs and Visit Day1 Vital Signs have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, ND should be recorded HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 18:14:02
User entered '175.2' cm	Yaa Ofori-Marfoh (b) (4) (b) (4)	28 Aug 2020 15:28:25

US3692001

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:24:06

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered missing code ND - Not Done; reason for change Data Entry Error	Mandy Tipton (b) (4) (b) (4)	09 Sep 2020 21:20:06
User entered '75' kg	Yaa Ofori-Marfoh (b) (4) (b) (4)	28 Aug 2020 15:28:25

US3692001

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:06

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User accepted default value 'Post-Dose (POSTDOSE)'	Yaa Ofori-Marfoh (b) (4) (b) (4)	28 Aug 2020 15:28:25

US3692001

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:06

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered 'Yes (Y)'	Yaa Ofori-Marfoh (b) (4) (b) (4)	28 Aug 2020 15:28:25

US3692001

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:06

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered '26 Aug 2020'	Yaa Ofori-Marfoh (b) (4) (b) (4)	28 Aug 2020 15:28:25

US3692001

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:06

Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User closed query 'Data is required. Please provide.' (Site from System).	System	31 Aug 2020 18:10:58
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	31 Aug 2020 18:10:58
User entered '17:48' reason for change: Data Entry Error	Abigail Riddick (b) (4) (b) (4)	31 Aug 2020 18:10:58
User opened query 'Data is required. Please provide.' (Site from System).	System	28 Aug 2020 15:28:25
User entered empty.	Yaa Ofori-Marfoh (b) (4) (b) (4)	28 Aug 2020 15:28:25

US3692001

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:06

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User entered '26 Aug 2020 17:48'	System	31 Aug 2020 18:10:58
User entered empty.	System	28 Aug 2020 15:28:25

US3692001

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:06

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered '36.1' C	Yaa Ofori-Marfoh (b) (4) (b) (4)	28 Aug 2020 15:28:25

US3692001

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:06

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User closed query 'Data is required. Please provide.' (Site from System).	System	31 Aug 2020 18:11:11
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	31 Aug 2020 18:11:11
User entered 'Oral (Oral)' reason for change: Data Entry Error	Abigail Riddick (b) (4) (b) (4)	31 Aug 2020 18:11:11
User opened query 'Data is required. Please provide.' (Site from System).	System	28 Aug 2020 15:28:25
User entered empty.	Yaa Ofori-Marfoh (b) (4) (b) (4)	28 Aug 2020 15:28:25

US3692001

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:06

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered empty.	Yaa Ofori-Marfoh (b) (4) (b) (4)	28 Aug 2020 15:28:25

Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:24:06

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered '66' reason for change: Data Entry Error	Abigail Riddick (b) (4) (b) (4)	31 Aug 2020 18:12:29
User entered '70'	Yaa Ofori-Marfoh (b) (4) (b) (4)	28 Aug 2020 15:28:25

US3692001
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:24:06
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User entered 'bpm'	System	28 Aug 2020 15:28:25

US3692001

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:06

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered '18'	Yaa Ofori-Marfoh (b) (4) (b) (4)	28 Aug 2020 15:28:25

US3692001

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:06

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User entered 'breaths/min'	System	28 Aug 2020 15:28:25

US3692001

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:06

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered '121'	Yaa Ofori-Marfoh (b) (4) (b) (4)	28 Aug 2020 15:28:25

US3692001

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:06

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User entered 'mmHg'	System	28 Aug 2020 15:28:25

US3692001

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:06

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered '74'	Yaa Ofori-Marfoh (b) (4) (b) (4)	28 Aug 2020 15:28:25

US3692001

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:06

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User entered 'mmHg'	System	28 Aug 2020 15:28:25

Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 10 Jun 2021 09:24:06
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered 'Yes (Y)'	Yaa Ofori-Marfoh (b) (4) (b) (4)	28 Aug 2020 15:29:28

FDA-CBER-2022-1614-3322017

US3692001

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:24:06

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User closed query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	28 Aug 2020 15:29:37
User closed query 'The physical examination date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	28 Aug 2020 15:29:37
User entered '26 Aug 2020' reason for change: Data Entry Error	Yaa Ofori-Marfoh (b) (4) (b) (4)	28 Aug 2020 15:29:37
User opened query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	28 Aug 2020 15:29:28
User opened query 'The physical examination date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	28 Aug 2020 15:29:28
User entered '24 Aug 2020'	Yaa Ofori-Marfoh (b) (4) (b) (4)	28 Aug 2020 15:29:28

US3692001
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:24:06
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered 'Yes (Y)'	Becky Straub (b) (4)	26 Aug 2020 21:37:17

US3692001
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:24:06
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered empty.	Becky Straub (b) (4)	26 Aug 2020 21:37:17

US3692001

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:24:06

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered empty.	Becky Straub (b) (4)	26 Aug 2020 21:37:17

US3692001
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:24:06
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User entered 'MRNA-1273 OR PLACEBO'	System	26 Aug 2020 21:37:17

Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:24:06

What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered '26 Aug 2020'	Becky Straub (b) (4)	26 Aug 2020 21:37:17

FDA-CBER-2022-1614-3322023

Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:24:06

What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:45:25
User entered '17:17'	(b) (4) Becky Straub (b) (4)	26 Aug 2020 21:37:17

FDA-CBER-2022-1614-3322024

US3692001
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:24:06
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User entered '26 Aug 2020 17:17'	System	26 Aug 2020 21:37:17

US3692001

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:24:06

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered 'Left Arm (LEFT ARM)'	Becky Straub (b) (4)	26 Aug 2020 21:37:17

FDA-CBER-2022-1614-3322026

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User entered 'ONCE'	System	26 Aug 2020 21:37:17

FDA-CBER-2022-1614-3322027

US3692001
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:24:06
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User entered 'INTRAMUSCULAR'	System	26 Aug 2020 21:37:17

FDA-CBER-2022-1614-3322028

US3692001

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:24:06

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered 'Yes (Y)'	Mandy Tipton (b) (4) (b) (4)	01 Sep 2020 19:45:04

Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:24:06
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered '26 Aug 2020'	Mandy Tipton (b) (4) (b) (4)	01 Sep 2020 19:45:04

Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered '14:39'	Mandy Tipton (b) (4) (b) (4)	01 Sep 2020 19:45:04

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User entered '26 Aug 2020 14:39'	System	01 Sep 2020 19:45:04

FDA-CBER-2022-1614-3322032

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:24:06

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered '26 Aug 2020'	Mandy Tipton (b) (4) (b) (4)	01 Sep 2020 19:45:23

US3692001

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:24:06

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Mandy Tipton (b) (4) (b) (4)	01 Sep 2020 19:45:23

US3692001

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:24:06

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered 'Yes (Y)'	Mandy Tipton (b) (4) (b) (4)	01 Sep 2020 19:45:23

US3692001

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:24:06

Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered '14:53'	Mandy Tipton (b) (4) (b) (4)	01 Sep 2020 19:45:23

US3692001

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:24:06

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User entered '26 Aug 2020 14:53'	System	01 Sep 2020 19:45:23

US3692001

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:24:06

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Mandy Tipton (b) (4) (b) (4)	01 Sep 2020 19:45:23

US3692001

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:24:06

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered 'No (N)'	Mandy Tipton (b) (4) (b) (4)	01 Sep 2020 19:45:23

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:24:06

Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered empty.	Mandy Tipton (b) (4) (b) (4)	01 Sep 2020 19:45:23

US3692001

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:24:06

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User entered empty.	System	01 Sep 2020 19:45:23

US3692001
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 10 Jun 2021 09:24:06

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered 'Yes (Y)'	Yaa Ofori-Marfoh (b) (4) (b) (4)	28 Aug 2020 15:33:32

US3692001
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 10 Jun 2021 09:24:06
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User entered '1'	System	28 Aug 2020 15:33:32

US3692001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
Data entry locked.	System	26 Aug 2020 21:37:17
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 21:37:17

US3692001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:24:06
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-26T17:53:24', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '6d99c757-5bef-4ea0-9fb3-2110418dbff6'	System	26 Aug 2020 21:54:06
User entered 'Yes (Y)'	System	26 Aug 2020 21:54:06

US3692001

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:24:06

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-26T17:53:57', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '6d99c757-5bef-4ea0-9fb3-2110418dbff6'	System	26 Aug 2020 21:54:06
User entered '97.0'	System	26 Aug 2020 21:54:06

US3692001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:24:06

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-26T17:54:01', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '6d99c757-5bef-4ea0-9fb3-2110418dbff6'	System	26 Aug 2020 21:54:06
User entered 'No (N)'	System	26 Aug 2020 21:54:06

US3692001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:24:06
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-26T17:54:05', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '6d99c757-5bef-4ea0-9fb3-2110418dbff6'	System	26 Aug 2020 21:54:06
User entered '26 Aug 2020 17:54'	System	26 Aug 2020 21:54:06

US3692001

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:24:06

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
User entered '26 Aug 2020 17:37'	System	26 Aug 2020 21:37:17

US3692001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:24:06
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
User entered '26 Aug 2020 20:07'	System	26 Aug 2020 21:37:17

US3692001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
Data entry locked.	System	26 Aug 2020 21:37:17
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 21:37:17

US3692001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:24:06
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-27T10:30:09', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '72634b1b-b9a9-474f-8663-b7f597927984'	System	27 Aug 2020 14:30:58
User entered 'Yes (Y)'	System	27 Aug 2020 14:30:58

US3692001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:24:06

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-27T10:30:47', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '72634b1b-b9a9-474f-8663-b7f597927984'	System	27 Aug 2020 14:30:58
User entered '97.9'	System	27 Aug 2020 14:30:58

US3692001

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:24:06

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-27T10:30:53', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '72634b1b-b9a9-474f-8663-b7f597927984'	System	27 Aug 2020 14:30:58
User entered 'No (N)'	System	27 Aug 2020 14:30:58

US3692001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:24:06
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-27T10:30:56', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '72634b1b-b9a9-474f-8663-b7f597927984'	System	27 Aug 2020 14:30:58
User entered '27 Aug 2020 10:30'	System	27 Aug 2020 14:30:58

US3692001

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:24:06

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
User entered '26 Aug 2020 21:02'	System	26 Aug 2020 21:37:17

US3692001

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:24:06

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 21:37:17

US3692001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
Data entry locked.	System	26 Aug 2020 21:37:17
User entered 'Day 2'	System	26 Aug 2020 21:37:17

US3692001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:24:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-27T17:37:09', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '59129885-6751-4eea-ae12-adc6d3c1a2a2'	System	27 Aug 2020 22:37:25
User entered 'Yes (Y)'	System	27 Aug 2020 22:37:25

US3692001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:24:06

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-27T17:37:15', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '59129885-6751-4eea-ae12-adc6d3c1a2a2'	System	27 Aug 2020 22:37:25
User entered '97.5'	System	27 Aug 2020 22:37:25

US3692001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:24:06
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-27T17:37:18', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '59129885-6751-4eea-ae12-adc6d3c1a2a2'	System	27 Aug 2020 22:37:25
User entered 'No (N)'	System	27 Aug 2020 22:37:25

FDA-CBER-2022-1614-3322061

US3692001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:24:06
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-27T17:37:21', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '59129885-6751-4eea-ae12-adc6d3c1a2a2'	System	27 Aug 2020 22:37:25
User entered '27 Aug 2020 17:37'	System	27 Aug 2020 22:37:25

US3692001

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:24:06

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 21:37:17

US3692001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:24:06

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 21:37:17

US3692001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
Data entry locked.	System	26 Aug 2020 21:37:17
User entered 'Day 3'	System	26 Aug 2020 21:37:17

US3692001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:24:06
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-28T15:23:08', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'a6b730f0-6ad2-4031-9b41-d322f71bd22c'	System	28 Aug 2020 20:23:21
User entered 'Yes (Y)'	System	28 Aug 2020 20:23:21

US3692001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:24:06

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-28T15:23:12', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'a6b730f0-6ad2-4031-9b41-d322f71bd22c'	System	28 Aug 2020 20:23:21
User entered '98.0'	System	28 Aug 2020 20:23:21

US3692001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:24:06

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-28T15:23:16', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'a6b730f0-6ad2-4031-9b41-d322f71bd22c'	System	28 Aug 2020 20:23:21
User entered 'No (N)'	System	28 Aug 2020 20:23:21

US3692001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:24:06
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-28T15:23:19', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'a6b730f0-6ad2-4031-9b41-d322f71bd22c'	System	28 Aug 2020 20:23:21
User entered '28 Aug 2020 15:23'	System	28 Aug 2020 20:23:21

US3692001

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:24:06

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 21:37:17

US3692001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:24:06

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 21:37:17

US3692001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
Data entry locked.	System	26 Aug 2020 21:37:17
User entered 'Day 4'	System	26 Aug 2020 21:37:17

US3692001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:24:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-29T19:32:50', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '84158aa7-d6f3-4631-bf0f-37e4548d1079'	System	30 Aug 2020 01:33:34
User entered 'Yes (Y)'	System	30 Aug 2020 01:33:34

US3692001

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:24:06

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-29T19:33:18', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '84158aa7-d6f3-4631-bf0f-37e4548d1079'	System	30 Aug 2020 01:33:34
User entered '98.0'	System	30 Aug 2020 01:33:34

US3692001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:24:06

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-29T19:33:24', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '84158aa7-d6f3-4631-bf0f-37e4548d1079'	System	30 Aug 2020 01:33:34
User entered 'No (N)'	System	30 Aug 2020 01:33:34

US3692001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:24:06
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-29T19:33:30', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '84158aa7-d6f3-4631-bf0f-37e4548d1079'	System	30 Aug 2020 01:33:34
User entered '29 Aug 2020 19:33'	System	30 Aug 2020 01:33:34

US3692001

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:24:06

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 21:37:17

US3692001

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:24:06

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 21:37:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
Data entry locked.	System	26 Aug 2020 21:37:17
User entered 'Day 5'	System	26 Aug 2020 21:37:17

US3692001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:24:06
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-30T18:21:50', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '9d1c1002-08a8-4c0d-9b58-9e81abd232fe'	System	31 Aug 2020 00:22:04
User entered 'Yes (Y)'	System	31 Aug 2020 00:22:04

US3692001

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:24:06

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-30T18:21:55', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '9d1c1002-08a8-4c0d-9b58-9e81abd232fe'	System	31 Aug 2020 00:22:04
User entered '97.9'	System	31 Aug 2020 00:22:04

US3692001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:24:06

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-30T18:21:58', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '9d1c1002-08a8-4c0d-9b58-9e81abd232fe'	System	31 Aug 2020 00:22:04
User entered 'No (N)'	System	31 Aug 2020 00:22:04

US3692001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:24:06
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-30T18:22:00', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '9d1c1002-08a8-4c0d-9b58-9e81abd232fe'	System	31 Aug 2020 00:22:04
User entered '30 Aug 2020 18:22'	System	31 Aug 2020 00:22:04

US3692001

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:24:06

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 21:37:17

US3692001

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:24:06

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 21:37:17

US3692001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
Data entry locked.	System	26 Aug 2020 21:37:17
User entered 'Day 6'	System	26 Aug 2020 21:37:17

US3692001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:24:06
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-31T18:57:45', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'd45c772a-8e85-4f90-a2d9-971541c3aa6c'	System	01 Sep 2020 00:58:01
User entered 'Yes (Y)'	System	01 Sep 2020 00:58:01

FDA-CBER-2022-1614-3322087

US3692001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:24:06

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-31T18:57:51', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'd45c772a-8e85-4f90-a2d9-971541c3aa6c'	System	01 Sep 2020 00:58:01
User entered '98.0'	System	01 Sep 2020 00:58:01

US3692001

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:24:06

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-31T18:57:54', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'd45c772a-8e85-4f90-a2d9-971541c3aa6c'	System	01 Sep 2020 00:58:01
User entered 'No (N)'	System	01 Sep 2020 00:58:01

US3692001

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:24:06

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-31T18:57:56', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'd45c772a-8e85-4f90-a2d9-971541c3aa6c'	System	01 Sep 2020 00:58:01
User entered '31 Aug 2020 18:57'	System	01 Sep 2020 00:58:01

US3692001

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:24:06

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 21:37:17

US3692001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:24:06
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 21:37:17

US3692001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
Data entry locked.	System	26 Aug 2020 21:37:17
User entered 'Day 7'	System	26 Aug 2020 21:37:17

US3692001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:24:06
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-01T17:55:09', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '0a703770-f53e-4c0b-aece-44e5095ebe14'	System	01 Sep 2020 23:55:38
User entered 'Yes (Y)'	System	01 Sep 2020 23:55:38

US3692001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:24:06

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-01T17:55:14', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '0a703770-f53e-4c0b-aece-44e5095ebe14'	System	01 Sep 2020 23:55:38
User entered '98.1'	System	01 Sep 2020 23:55:38

US3692001

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:24:06

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-01T17:55:17', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '0a703770-f53e-4c0b-aece-44e5095ebe14'	System	01 Sep 2020 23:55:38
User entered 'No (N)'	System	01 Sep 2020 23:55:38

US3692001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:24:06
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-01T17:55:35', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '0a703770-f53e-4c0b-aece-44e5095ebe14'	System	01 Sep 2020 23:55:38
User entered '01 Sep 2020 17:55'	System	01 Sep 2020 23:55:38

US3692001

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:24:06

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 21:37:17

US3692001
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:24:06
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 21:37:17

US3692001
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
Data entry locked.	System	26 Aug 2020 21:37:17
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 21:37:17

US3692001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:24:06

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-26T17:54:11', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'e52f87e3-d3dc-40d6-b431-c439dfce4aa2'	System	26 Aug 2020 21:54:24
User entered 'None (1)'	System	26 Aug 2020 21:54:24

FDA-CBER-2022-1614-3322101

US3692001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:24:06

Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-26T17:54:14', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'e52f87e3-d3dc-40d6-b431-c439dfce4aa2'	System	26 Aug 2020 21:54:24
User entered 'No (N)'	System	26 Aug 2020 21:54:24

US3692001
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:24:06
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-26T17:54:17', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'e52f87e3-d3dc-40d6-b431-c439dfce4aa2'	System	26 Aug 2020 21:54:24
User entered 'No (N)'	System	26 Aug 2020 21:54:24

US3692001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:24:06

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-26T17:54:20', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'e52f87e3-d3dc-40d6-b431-c439dfce4aa2'	System	26 Aug 2020 21:54:24
User entered 'None (1)'	System	26 Aug 2020 21:54:24

US3692001
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:24:06
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-26T17:54:23', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'e52f87e3-d3dc-40d6-b431-c439dfce4aa2'	System	26 Aug 2020 21:54:24
User entered '26 Aug 2020 17:54'	System	26 Aug 2020 21:54:24

US3692001
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:24:06
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
User entered '26 Aug 2020 17:37'	System	26 Aug 2020 21:37:17

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
User entered '26 Aug 2020 20:07'	System	26 Aug 2020 21:37:17

FDA-CBER-2022-1614-3322107

US3692001
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
Data entry locked.	System	26 Aug 2020 21:37:17
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 21:37:17

US3692001
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:24:06

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-27T10:31:01', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '62795ff9-3a5e-460e-b827-56a980cd5b30'	System	27 Aug 2020 14:31:15
User entered 'None (1)'	System	27 Aug 2020 14:31:15

US3692001
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:24:06
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-27T10:31:03', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '62795ff9-3a5e-460e-b827-56a980cd5b30'	System	27 Aug 2020 14:31:15
User entered 'No (N)'	System	27 Aug 2020 14:31:15

US3692001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:24:06

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-27T10:31:06', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '62795ff9-3a5e-460e-b827-56a980cd5b30'	System	27 Aug 2020 14:31:15
User entered 'No (N)'	System	27 Aug 2020 14:31:15

US3692001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:24:06

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-27T10:31:08', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '62795ff9-3a5e-460e-b827-56a980cd5b30'	System	27 Aug 2020 14:31:15
User entered 'None (1)'	System	27 Aug 2020 14:31:15

US3692001
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:24:06
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-27T10:31:11', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '62795ff9-3a5e-460e-b827-56a980cd5b30'	System	27 Aug 2020 14:31:15
User entered '27 Aug 2020 10:31'	System	27 Aug 2020 14:31:15

US3692001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:24:06

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
User entered '26 Aug 2020 21:02'	System	26 Aug 2020 21:37:17

US3692001
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:24:06
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 21:37:17

US3692001
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
Data entry locked.	System	26 Aug 2020 21:37:17
User entered 'Day 2'	System	26 Aug 2020 21:37:17

US3692001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:24:06

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-27T17:37:25', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '5fb7b7ef-fee4-4a04-b794-ce5b068d7f65'	System	27 Aug 2020 22:37:41
User entered 'None (1)'	System	27 Aug 2020 22:37:41

US3692001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:24:06

Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-27T17:37:28', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '5fb7b7ef-fee4-4a04-b794-ce5b068d7f65'	System	27 Aug 2020 22:37:41
User entered 'No (N)'	System	27 Aug 2020 22:37:41

US3692001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:24:06

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-27T17:37:31', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '5fb7b7ef-fee4-4a04-b794-ce5b068d7f65'	System	27 Aug 2020 22:37:41
User entered 'No (N)'	System	27 Aug 2020 22:37:41

US3692001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:24:06

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-27T17:37:34', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '5fb7b7ef-fee4-4a04-b794-ce5b068d7f65'	System	27 Aug 2020 22:37:41
User entered 'None (1)'	System	27 Aug 2020 22:37:41

US3692001
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:24:06
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-27T17:37:36', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '5fb7b7ef-fee4-4a04-b794-ce5b068d7f65'	System	27 Aug 2020 22:37:41
User entered '27 Aug 2020 17:37'	System	27 Aug 2020 22:37:41

US3692001
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:24:06
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 21:37:17

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 21:37:17

FDA-CBER-2022-1614-3322123

US3692001
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
Data entry locked.	System	26 Aug 2020 21:37:17
User entered 'Day 3'	System	26 Aug 2020 21:37:17

US3692001
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:24:06

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-28T15:23:22', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '25e53bc5-a2d6-4840-82d6-a0700fdff68e'	System	28 Aug 2020 20:23:33
User entered 'None (1)'	System	28 Aug 2020 20:23:33

US3692001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:24:06

Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-28T15:23:25', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '25e53bc5-a2d6-4840-82d6-a0700fdff68e'	System	28 Aug 2020 20:23:33
User entered 'No (N)'	System	28 Aug 2020 20:23:33

US3692001
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:24:06
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-28T15:23:27', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '25e53bc5-a2d6-4840-82d6-a0700fdff68e'	System	28 Aug 2020 20:23:33
User entered 'No (N)'	System	28 Aug 2020 20:23:33

US3692001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:24:06

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-28T15:23:29', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '25e53bc5-a2d6-4840-82d6-a0700fdff68e'	System	28 Aug 2020 20:23:33
User entered 'None (1)'	System	28 Aug 2020 20:23:33

US3692001
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:24:06
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-28T15:23:31', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '25e53bc5-a2d6-4840-82d6-a0700fdff68e'	System	28 Aug 2020 20:23:33
User entered '28 Aug 2020 15:23'	System	28 Aug 2020 20:23:33

US3692001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:24:06

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 21:37:17

US3692001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:24:06

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 21:37:17

US3692001
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
Data entry locked.	System	26 Aug 2020 21:37:17
User entered 'Day 4'	System	26 Aug 2020 21:37:17

US3692001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:24:06

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-29T19:33:40', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '77614ca4-3d8a-43eb-b5cd-a48d4f2ae1f2'	System	30 Aug 2020 01:34:01
User entered 'None (1)'	System	30 Aug 2020 01:34:01

US3692001
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:24:06
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-29T19:33:44', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '77614ca4-3d8a-43eb-b5cd-a48d4f2ae1f2'	System	30 Aug 2020 01:34:01
User entered 'No (N)'	System	30 Aug 2020 01:34:01

US3692001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:24:06

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-29T19:33:47', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '77614ca4-3d8a-43eb-b5cd-a48d4f2ae1f2'	System	30 Aug 2020 01:34:01
User entered 'No (N)'	System	30 Aug 2020 01:34:01

US3692001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:24:06

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-29T19:33:55', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '77614ca4-3d8a-43eb-b5cd-a48d4f2ae1f2'	System	30 Aug 2020 01:34:01
User entered 'None (1)'	System	30 Aug 2020 01:34:01

US3692001
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:24:06
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-29T19:33:59', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '77614ca4-3d8a-43eb-b5cd-a48d4f2ae1f2'	System	30 Aug 2020 01:34:01
User entered '29 Aug 2020 19:33'	System	30 Aug 2020 01:34:01

US3692001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:24:06

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 21:37:17

US3692001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:24:06

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 21:37:17

US3692001
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
Data entry locked.	System	26 Aug 2020 21:37:17
User entered 'Day 5'	System	26 Aug 2020 21:37:17

US3692001
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:24:06

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-30T18:22:04', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '10b52588-9cc6-420c-9e7d-794d4473fd23'	System	31 Aug 2020 00:22:17
User entered 'None (1)'	System	31 Aug 2020 00:22:17

US3692001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:24:06

Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-30T18:22:06', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '10b52588-9cc6-420c-9e7d-794d4473fd23'	System	31 Aug 2020 00:22:17
User entered 'No (N)'	System	31 Aug 2020 00:22:17

US3692001
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:24:06
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-30T18:22:08', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '10b52588-9cc6-420c-9e7d-794d4473fd23'	System	31 Aug 2020 00:22:17
User entered 'No (N)'	System	31 Aug 2020 00:22:17

US3692001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:24:06

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-30T18:22:10', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '10b52588-9cc6-420c-9e7d-794d4473fd23'	System	31 Aug 2020 00:22:17
User entered 'None (1)'	System	31 Aug 2020 00:22:17

US3692001
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:24:06
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-30T18:22:13', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '10b52588-9cc6-420c-9e7d-794d4473fd23'	System	31 Aug 2020 00:22:17
User entered '30 Aug 2020 18:22'	System	31 Aug 2020 00:22:17

US3692001
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:24:06
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 21:37:17

US3692001
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:24:06
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 21:37:17

Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
Data entry locked.	System	26 Aug 2020 21:37:17
User entered 'Day 6'	System	26 Aug 2020 21:37:17

US3692001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:24:06

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-31T18:58:00', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '7210018a-edf0-4055-823b-7c5bfc29661e'	System	01 Sep 2020 00:58:11
User entered 'None (1)'	System	01 Sep 2020 00:58:11

US3692001
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:24:06
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-31T18:58:02', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '7210018a-edf0-4055-823b-7c5bfc29661e'	System	01 Sep 2020 00:58:11
User entered 'No (N)'	System	01 Sep 2020 00:58:11

US3692001
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:24:06
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-31T18:58:04', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '7210018a-edf0-4055-823b-7c5bfc29661e'	System	01 Sep 2020 00:58:11
User entered 'No (N)'	System	01 Sep 2020 00:58:11

US3692001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:24:06

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-31T18:58:07', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '7210018a-edf0-4055-823b-7c5bfc29661e'	System	01 Sep 2020 00:58:11
User entered 'None (1)'	System	01 Sep 2020 00:58:11

US3692001
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:24:06
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-31T18:58:09', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '7210018a-edf0-4055-823b-7c5bfc29661e'	System	01 Sep 2020 00:58:11
User entered '31 Aug 2020 18:58'	System	01 Sep 2020 00:58:11

US3692001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:24:06

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 21:37:17

US3692001
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:24:06
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 21:37:17

US3692001
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
Data entry locked.	System	26 Aug 2020 21:37:17
User entered 'Day 7'	System	26 Aug 2020 21:37:17

US3692001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:24:06

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-01T17:55:38', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '4d17e6c1-1605-4ad0-ac09-733f7973ce78'	System	01 Sep 2020 23:55:49
User entered 'None (1)'	System	01 Sep 2020 23:55:49

US3692001
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:24:06
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-01T17:55:41', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '4d17e6c1-1605-4ad0-ac09-733f7973ce78'	System	01 Sep 2020 23:55:49
User entered 'No (N)'	System	01 Sep 2020 23:55:49

US3692001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:24:06

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-01T17:55:43', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '4d17e6c1-1605-4ad0-ac09-733f7973ce78'	System	01 Sep 2020 23:55:49
User entered 'No (N)'	System	01 Sep 2020 23:55:49

US3692001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:24:06

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-01T17:55:45', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '4d17e6c1-1605-4ad0-ac09-733f7973ce78'	System	01 Sep 2020 23:55:49
User entered 'None (1)'	System	01 Sep 2020 23:55:49

US3692001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:24:06

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-01T17:55:48', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '4d17e6c1-1605-4ad0-ac09-733f7973ce78'	System	01 Sep 2020 23:55:49
User entered '01 Sep 2020 17:55'	System	01 Sep 2020 23:55:49

US3692001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:24:06

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 21:37:17

US3692001

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:24:06

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 21:37:17

US3692001
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
Data entry locked.	System	26 Aug 2020 21:37:17
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 21:37:17

US3692001
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:24:06
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-26T17:54:27', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '915f79a7-dacf-4cd6-9251-632cf2d466ae'	System	26 Aug 2020 21:54:46
User entered 'None (0)'	System	26 Aug 2020 21:54:46

US3692001
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:24:06
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-26T17:54:29', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '915f79a7-dacf-4cd6-9251-632cf2d466ae'	System	26 Aug 2020 21:54:46
User entered 'None (0)'	System	26 Aug 2020 21:54:46

US3692001
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:24:06
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-26T17:54:32', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '915f79a7-dacf-4cd6-9251-632cf2d466ae'	System	26 Aug 2020 21:54:46
User entered 'None (0)'	System	26 Aug 2020 21:54:46

US3692001
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:24:06
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-26T17:54:34', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '915f79a7-dacf-4cd6-9251-632cf2d466ae'	System	26 Aug 2020 21:54:46
User entered 'None (0)'	System	26 Aug 2020 21:54:46

US3692001
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:24:06
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-26T17:54:36', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '915f79a7-dacf-4cd6-9251-632cf2d466ae'	System	26 Aug 2020 21:54:46
User entered 'None (0)'	System	26 Aug 2020 21:54:46

US3692001
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:24:06
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-26T17:54:38', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '915f79a7-dacf-4cd6-9251-632cf2d466ae'	System	26 Aug 2020 21:54:46
User entered 'None (0)'	System	26 Aug 2020 21:54:46

US3692001
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:24:06

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-26T17:54:41', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '915f79a7-dacf-4cd6-9251-632cf2d466ae'	System	26 Aug 2020 21:54:46
User entered 'No (N)'	System	26 Aug 2020 21:54:46

US3692001

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:24:06

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-26T17:54:44', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '915f79a7-dacf-4cd6-9251-632cf2d466ae'	System	26 Aug 2020 21:54:46
User entered '26 Aug 2020 17:54'	System	26 Aug 2020 21:54:46

US3692001

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:24:06

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
User entered '26 Aug 2020 17:37'	System	26 Aug 2020 21:37:17

US3692001

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:24:06

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
User entered '26 Aug 2020 20:07'	System	26 Aug 2020 21:37:17

US3692001
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
Data entry locked.	System	26 Aug 2020 21:37:17
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 21:37:17

US3692001
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:24:06
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-27T10:31:14', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'c48a141c-0b42-45ad-b35a-b049f86454ea'	System	27 Aug 2020 14:31:30
User entered 'None (0)'	System	27 Aug 2020 14:31:30

US3692001
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:24:06
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-27T10:31:16', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'c48a141c-0b42-45ad-b35a-b049f86454ea'	System	27 Aug 2020 14:31:30
User entered 'None (0)'	System	27 Aug 2020 14:31:30

US3692001
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:24:06
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-27T10:31:17', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'c48a141c-0b42-45ad-b35a-b049f86454ea'	System	27 Aug 2020 14:31:30
User entered 'None (0)'	System	27 Aug 2020 14:31:30

US3692001
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:24:06
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-27T10:31:19', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'c48a141c-0b42-45ad-b35a-b049f86454ea'	System	27 Aug 2020 14:31:30
User entered 'None (0)'	System	27 Aug 2020 14:31:30

US3692001
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:24:06
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-27T10:31:21', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'c48a141c-0b42-45ad-b35a-b049f86454ea'	System	27 Aug 2020 14:31:30
User entered 'None (0)'	System	27 Aug 2020 14:31:30

US3692001
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:24:06
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-27T10:31:23', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'c48a141c-0b42-45ad-b35a-b049f86454ea'	System	27 Aug 2020 14:31:30
User entered 'None (0)'	System	27 Aug 2020 14:31:30

US3692001

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:24:06

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-27T10:31:24', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'c48a141c-0b42-45ad-b35a-b049f86454ea'	System	27 Aug 2020 14:31:30
User entered 'No (N)'	System	27 Aug 2020 14:31:30

US3692001
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:24:06
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-27T10:31:27', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'c48a141c-0b42-45ad-b35a-b049f86454ea'	System	27 Aug 2020 14:31:30
User entered '27 Aug 2020 10:31'	System	27 Aug 2020 14:31:30

US3692001

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:24:06

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
User entered '26 Aug 2020 21:02'	System	26 Aug 2020 21:37:17

US3692001

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:24:06

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 21:37:17

US3692001
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
Data entry locked.	System	26 Aug 2020 21:37:17
User entered 'Day 2'	System	26 Aug 2020 21:37:17

US3692001
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:24:06
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-27T17:37:40', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'b96f1dd6-c61f-41ed-bc3d-23d6fb1a33d4'	System	27 Aug 2020 22:37:56
User entered 'None (0)'	System	27 Aug 2020 22:37:56

US3692001
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:24:06
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-27T17:37:41', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'b96f1dd6-c61f-41ed-bc3d-23d6fb1a33d4'	System	27 Aug 2020 22:37:56
User entered 'None (0)'	System	27 Aug 2020 22:37:56

US3692001
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:24:06
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-27T17:37:43', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'b96f1dd6-c61f-41ed-bc3d-23d6fb1a33d4'	System	27 Aug 2020 22:37:56
User entered 'None (0)'	System	27 Aug 2020 22:37:56

US3692001
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:24:06
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-27T17:37:45', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'b96f1dd6-c61f-41ed-bc3d-23d6fb1a33d4'	System	27 Aug 2020 22:37:56
User entered 'None (0)'	System	27 Aug 2020 22:37:56

US3692001
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:24:06
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-27T17:37:47', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'b96f1dd6-c61f-41ed-bc3d-23d6fb1a33d4'	System	27 Aug 2020 22:37:56
User entered 'None (0)'	System	27 Aug 2020 22:37:56

US3692001
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:24:06
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-27T17:37:49', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'b96f1dd6-c61f-41ed-bc3d-23d6fb1a33d4'	System	27 Aug 2020 22:37:56
User entered 'None (0)'	System	27 Aug 2020 22:37:56

US3692001

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:24:06

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-27T17:37:51', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'b96f1dd6-c61f-41ed-bc3d-23d6fb1a33d4'	System	27 Aug 2020 22:37:56
User entered 'No (N)'	System	27 Aug 2020 22:37:56

US3692001

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:24:06

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-27T17:37:53', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'b96f1dd6-c61f-41ed-bc3d-23d6fb1a33d4'	System	27 Aug 2020 22:37:56
User entered '27 Aug 2020 17:37'	System	27 Aug 2020 22:37:56

US3692001

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:24:06

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 21:37:17

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 21:37:17

FDA-CBER-2022-1614-3322196

Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
Data entry locked.	System	26 Aug 2020 21:37:17
User entered 'Day 3'	System	26 Aug 2020 21:37:17

FDA-CBER-2022-1614-3322197

US3692001
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:24:06
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-28T15:23:36', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '27c0e2c8-f0ba-4ed7-8cb9-5780a3fded65'	System	28 Aug 2020 20:23:52
User entered 'None (0)'	System	28 Aug 2020 20:23:52

US3692001
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:24:06
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-28T15:23:37', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '27c0e2c8-f0ba-4ed7-8cb9-5780a3fded65'	System	28 Aug 2020 20:23:52
User entered 'None (0)'	System	28 Aug 2020 20:23:52

US3692001
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:24:06
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-28T15:23:39', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '27c0e2c8-f0ba-4ed7-8cb9-5780a3fded65'	System	28 Aug 2020 20:23:52
User entered 'None (0)'	System	28 Aug 2020 20:23:52

US3692001
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:24:06
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-28T15:23:41', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '27c0e2c8-f0ba-4ed7-8cb9-5780a3fded65'	System	28 Aug 2020 20:23:52
User entered 'None (0)'	System	28 Aug 2020 20:23:52

US3692001
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:24:06
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-28T15:23:43', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '27c0e2c8-f0ba-4ed7-8cb9-5780a3fded65'	System	28 Aug 2020 20:23:52
User entered 'None (0)'	System	28 Aug 2020 20:23:52

US3692001
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:24:06
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-28T15:23:45', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '27c0e2c8-f0ba-4ed7-8cb9-5780a3fded65'	System	28 Aug 2020 20:23:52
User entered 'None (0)'	System	28 Aug 2020 20:23:52

US3692001
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:24:06
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-28T15:23:48', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '27c0e2c8-f0ba-4ed7-8cb9-5780a3fded65'	System	28 Aug 2020 20:23:52
User entered 'No (N)'	System	28 Aug 2020 20:23:52

US3692001

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:24:06

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-28T15:23:50', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '27c0e2c8-f0ba-4ed7-8cb9-5780a3fded65'	System	28 Aug 2020 20:23:52
User entered '28 Aug 2020 15:23'	System	28 Aug 2020 20:23:52

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 21:37:17

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 21:37:17

US3692001
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
Data entry locked.	System	26 Aug 2020 21:37:17
User entered 'Day 4'	System	26 Aug 2020 21:37:17

US3692001
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:24:06
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-29T19:34:06', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '2834dc0e-3471-44e1-b257-97af09d46d8f'	System	30 Aug 2020 01:34:37
User entered 'None (0)'	System	30 Aug 2020 01:34:37

US3692001
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:24:06
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-29T19:34:09', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '2834dc0e-3471-44e1-b257-97af09d46d8f'	System	30 Aug 2020 01:34:37
User entered 'None (0)'	System	30 Aug 2020 01:34:37

US3692001
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:24:06
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-29T19:34:12', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '2834dc0e-3471-44e1-b257-97af09d46d8f'	System	30 Aug 2020 01:34:37
User entered 'None (0)'	System	30 Aug 2020 01:34:37

US3692001
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:24:06
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-29T19:34:15', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '2834dc0e-3471-44e1-b257-97af09d46d8f'	System	30 Aug 2020 01:34:37
User entered 'None (0)'	System	30 Aug 2020 01:34:37

US3692001
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:24:06
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-29T19:34:18', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '2834dc0e-3471-44e1-b257-97af09d46d8f'	System	30 Aug 2020 01:34:37
User entered 'None (0)'	System	30 Aug 2020 01:34:37

US3692001
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:24:06
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-29T19:34:20', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '2834dc0e-3471-44e1-b257-97af09d46d8f'	System	30 Aug 2020 01:34:37
User entered 'None (0)'	System	30 Aug 2020 01:34:37

US3692001

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:24:06

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-29T19:34:30', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '2834dc0e-3471-44e1-b257-97af09d46d8f'	System	30 Aug 2020 01:34:37
User entered 'No (N)'	System	30 Aug 2020 01:34:37

US3692001

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:24:06

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-29T19:34:34', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '2834dc0e-3471-44e1-b257-97af09d46d8f'	System	30 Aug 2020 01:34:37
User entered '29 Aug 2020 19:34'	System	30 Aug 2020 01:34:37

US3692001
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:24:06
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 21:37:17

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 21:37:17

US3692001
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
Data entry locked.	System	26 Aug 2020 21:37:17
User entered 'Day 5'	System	26 Aug 2020 21:37:17

US3692001
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:24:06
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-30T18:22:17', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '8442a7c7-8deb-4860-ac37-d5a51979f8c1'	System	31 Aug 2020 00:22:39
User entered 'None (0)'	System	31 Aug 2020 00:22:39

US3692001
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:24:06
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-30T18:22:18', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '8442a7c7-8deb-4860-ac37-d5a51979f8c1'	System	31 Aug 2020 00:22:39
User entered 'None (0)'	System	31 Aug 2020 00:22:39

US3692001
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:24:06
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-30T18:22:21', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '8442a7c7-8deb-4860-ac37-d5a51979f8c1'	System	31 Aug 2020 00:22:39
User entered 'None (0)'	System	31 Aug 2020 00:22:39

US3692001
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:24:06
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-30T18:22:23', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '8442a7c7-8deb-4860-ac37-d5a51979f8c1'	System	31 Aug 2020 00:22:39
User entered 'None (0)'	System	31 Aug 2020 00:22:39

US3692001
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:24:06
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-30T18:22:26', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '8442a7c7-8deb-4860-ac37-d5a51979f8c1'	System	31 Aug 2020 00:22:39
User entered 'None (0)'	System	31 Aug 2020 00:22:39

US3692001
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:24:06
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-30T18:22:28', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '8442a7c7-8deb-4860-ac37-d5a51979f8c1'	System	31 Aug 2020 00:22:39
User entered 'None (0)'	System	31 Aug 2020 00:22:39

US3692001

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:24:06

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-30T18:22:30', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '8442a7c7-8deb-4860-ac37-d5a51979f8c1'	System	31 Aug 2020 00:22:39
User entered 'No (N)'	System	31 Aug 2020 00:22:39

US3692001
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:24:06
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-30T18:22:33', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '8442a7c7-8deb-4860-ac37-d5a51979f8c1'	System	31 Aug 2020 00:22:39
User entered '30 Aug 2020 18:22'	System	31 Aug 2020 00:22:39

US3692001

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:24:06

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 21:37:17

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 21:37:17

US3692001
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
Data entry locked.	System	26 Aug 2020 21:37:17
User entered 'Day 6'	System	26 Aug 2020 21:37:17

US3692001
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:24:06
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-31T18:58:26', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '37aa4763-6d58-476a-89b3-7f05d70e8ae3'	System	01 Sep 2020 00:58:51
User entered 'None (0)'	System	01 Sep 2020 00:58:51

FDA-CBER-2022-1614-3322231

US3692001
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:24:06
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-31T18:58:29', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '37aa4763-6d58-476a-89b3-7f05d70e8ae3'	System	01 Sep 2020 00:58:51
User entered 'None (0)'	System	01 Sep 2020 00:58:51

US3692001
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:24:06
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-31T18:58:31', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '37aa4763-6d58-476a-89b3-7f05d70e8ae3'	System	01 Sep 2020 00:58:51
User entered 'None (0)'	System	01 Sep 2020 00:58:51

US3692001
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:24:06
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-31T18:58:34', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '37aa4763-6d58-476a-89b3-7f05d70e8ae3'	System	01 Sep 2020 00:58:51
User entered 'None (0)'	System	01 Sep 2020 00:58:51

US3692001
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:24:06
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-31T18:58:36', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '37aa4763-6d58-476a-89b3-7f05d70e8ae3'	System	01 Sep 2020 00:58:51
User entered 'None (0)'	System	01 Sep 2020 00:58:51

US3692001
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:24:06
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-31T18:58:40', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '37aa4763-6d58-476a-89b3-7f05d70e8ae3'	System	01 Sep 2020 00:58:51
User entered 'None (0)'	System	01 Sep 2020 00:58:51

US3692001
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:24:06

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-31T18:58:44', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '37aa4763-6d58-476a-89b3-7f05d70e8ae3'	System	01 Sep 2020 00:58:51
User entered 'No (N)'	System	01 Sep 2020 00:58:51

US3692001
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:24:06
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-08-31T18:58:47', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '37aa4763-6d58-476a-89b3-7f05d70e8ae3'	System	01 Sep 2020 00:58:51
User entered '31 Aug 2020 18:58'	System	01 Sep 2020 00:58:51

US3692001

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:24:06

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 21:37:17

US3692001

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:24:06

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 21:37:17

US3692001
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
Data entry locked.	System	26 Aug 2020 21:37:17
User entered 'Day 7'	System	26 Aug 2020 21:37:17

US3692001
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:24:06
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-01T17:55:51', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'a5e49758-b96d-456f-a367-881270f91708'	System	01 Sep 2020 23:56:08
User entered 'None (0)'	System	01 Sep 2020 23:56:08

US3692001
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:24:06
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-01T17:55:52', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'a5e49758-b96d-456f-a367-881270f91708'	System	01 Sep 2020 23:56:08
User entered 'None (0)'	System	01 Sep 2020 23:56:08

US3692001
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:24:06
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-01T17:55:54', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'a5e49758-b96d-456f-a367-881270f91708'	System	01 Sep 2020 23:56:08
User entered 'None (0)'	System	01 Sep 2020 23:56:08

US3692001
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:24:06
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-01T17:55:56', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'a5e49758-b96d-456f-a367-881270f91708'	System	01 Sep 2020 23:56:08
User entered 'None (0)'	System	01 Sep 2020 23:56:08

US3692001
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:24:06
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-01T17:55:59', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'a5e49758-b96d-456f-a367-881270f91708'	System	01 Sep 2020 23:56:08
User entered 'None (0)'	System	01 Sep 2020 23:56:08

US3692001
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:24:06
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-01T17:56:01', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'a5e49758-b96d-456f-a367-881270f91708'	System	01 Sep 2020 23:56:08
User entered 'None (0)'	System	01 Sep 2020 23:56:08

US3692001
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:24:06
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-01T17:56:03', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'a5e49758-b96d-456f-a367-881270f91708'	System	01 Sep 2020 23:56:08
User entered 'No (N)'	System	01 Sep 2020 23:56:08

US3692001
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:24:06
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-01T17:56:05', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'a5e49758-b96d-456f-a367-881270f91708'	System	01 Sep 2020 23:56:08
User entered '01 Sep 2020 17:56'	System	01 Sep 2020 23:56:08

US3692001
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:24:06
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 21:37:17

US3692001

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:24:06

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 21:37:17

US3692001
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:24:06

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered 'Yes (Y)'	Kristi Kirkland (b) (4) (b) (4)	02 Sep 2020 22:17:29

Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:24:06
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered '2 Sep 2020'	Kristi Kirkland (b) (4) (b) (4)	02 Sep 2020 22:17:29

US3692001

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:06

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered 'Contact Made (CONTACT MADE)'	Kristi Kirkland (b) (4) (b) (4)	02 Sep 2020 22:17:29

US3692001
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:24:06
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered empty.	Kristi Kirkland (b) (4) (b) (4)	02 Sep 2020 22:17:29

US3692001
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:24:06

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered 'Yes (Y)'	Kristi Kirkland (b) (4) (b) (4)	02 Sep 2020 22:17:34

US3692001
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:24:06
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User entered '1'	System	02 Sep 2020 22:17:34

US3692001
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:24:06

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered 'Yes (Y)'	Abigail Riddick (b) (4) (b) (4)	14 Sep 2020 17:31:28

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered '9 Sep 2020'	Abigail Riddick (b) (4) (b) (4)	14 Sep 2020 17:31:28

FDA-CBER-2022-1614-3322259

US3692001

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:06

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered 'Contact Made (CONTACT MADE)'	Abigail Riddick (b) (4) (b) (4)	14 Sep 2020 17:31:28

US3692001
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:24:06
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered empty.	Abigail Riddick (b) (4) (b) (4)	14 Sep 2020 17:31:28

US3692001
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:24:06

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered 'Yes (Y)'	Abigail Riddick (b) (4) (b) (4)	14 Sep 2020 17:31:33

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User entered '1'	System	14 Sep 2020 17:31:33

US3692001
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:24:06

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Sep 2020 14:43:49

FDA-CBER-2022-1614-3322264

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:45:25
User entered '16 Sep 2020'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:43:49

US3692001

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:06

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:45:25
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	17 Sep 2020 14:43:49

US3692001
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:24:06
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:45:25
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 14:43:49

US3692001

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:24:06

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:45:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Sep 2020 14:44:43

Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:24:06
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User entered '1'	System	17 Sep 2020 14:44:43

US3692001
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:24:06
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered 'Yes (Y)'	Mandy Tipton (b) (4) (b) (4)	23 Sep 2020 14:03:26

US3692001
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:24:06

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered '23 Sep 2020'	Mandy Tipton (b) (4) (b) (4)	23 Sep 2020 14:03:26

US3692001
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:24:06

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered 'Clinic (Clinic)'	Mandy Tipton (b) (4) (b) (4)	23 Sep 2020 14:03:26

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User entered 'VISIT2'	System	23 Sep 2020 14:03:26

US3692001

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:06

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	24 Sep 2020 11:37:38

US3692001

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:06

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:45:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 11:37:38

US3692001

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:06

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:45:25
User entered '23 Sep 2020'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 11:37:38

US3692001

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:06

Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered '08:18' reason for change: Data Entry Error	Mandy Tipton (b) (4) (b) (4)	25 Sep 2020 15:44:32
User entered '08:23'	(b) (4), (b) (6)	24 Sep 2020 11:37:38

US3692001

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:06

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User entered '23 Sep 2020 08:18'	System	25 Sep 2020 15:44:32
User entered '23 Sep 2020 08:23'	System	24 Sep 2020 11:37:38

US3692001

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:06

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered '36.3' C	(b) (4), (b) (6)	24 Sep 2020 11:37:38

US3692001

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:06

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:45:25
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 11:37:38

US3692001

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:06

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:45:25
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 11:37:38

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:45:25
User entered '75'	(b) (4), (b) (6)	24 Sep 2020 11:37:38

US3692001
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:24:06
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User entered 'bpm'	System	24 Sep 2020 11:37:38

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:45:25
User entered '18'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 11:37:38

FDA-CBER-2022-1614-3322284

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User entered 'breaths/min'	System	24 Sep 2020 11:37:38

Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:24:06

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:45:25
User entered '120'	(b) (4), (b) (6)	24 Sep 2020 11:37:38

FDA-CBER-2022-1614-3322286

US3692001

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:06

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User entered 'mmHg'	System	24 Sep 2020 11:37:38

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:45:25
User entered '78'	(b) (4), (b) (6)	24 Sep 2020 11:37:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User entered 'mmHg'	System	24 Sep 2020 11:37:38

US3692001

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:06

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	24 Sep 2020 11:37:38

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:45:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 11:37:38

US3692001

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:06

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:45:25
User entered '23 Sep 2020'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 11:37:38

US3692001

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:06

Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:45:25
User entered '10:28'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 11:37:38

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User entered '23 Sep 2020 10:28'	System	24 Sep 2020 11:37:38

FDA-CBER-2022-1614-3322294

US3692001

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:06

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:45:25
User entered '36.7' C	(b) (4), (b) (6)	24 Sep 2020 11:37:38

US3692001

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:06

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:45:25
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 11:37:38

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:45:25
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 11:37:38

US3692001

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:06

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:45:25
User entered '60'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 11:37:38

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User entered 'bpm'	System	24 Sep 2020 11:37:38

US3692001

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:06

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:45:25
User entered '17'	(b) (4), (b) (6)	24 Sep 2020 11:37:38

US3692001
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:24:06
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User entered 'breaths/min'	System	24 Sep 2020 11:37:38

US3692001

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:06

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered '114' reason for change: Data Entry Error	Mandy Tipton (b) (4) (b) (4)	25 Sep 2020 15:45:02
User entered '115'	(b) (4), (b) (6)	24 Sep 2020 11:37:38

US3692001

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:06

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User entered 'mmHg'	System	24 Sep 2020 11:37:38

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:45:25
User entered '74'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 11:37:38

FDA-CBER-2022-1614-3322304

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User entered 'mmHg'	System	24 Sep 2020 11:37:38

Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Generated On: 10 Jun 2021 09:24:06
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered 'Yes (Y)'	Mandy Tipton (b) (4) (b) (4)	23 Sep 2020 14:03:13

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered '23 Sep 2020'	Mandy Tipton (b) (4) (b) (4)	23 Sep 2020 14:03:13

US3692001
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:24:06
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered 'Yes (Y)'	Mandy Tipton (b) (4) (b) (4)	23 Sep 2020 14:02:38

US3692001
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:24:06
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered empty.	Mandy Tipton (b) (4) (b) (4)	23 Sep 2020 14:02:38

US3692001

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:24:06

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered empty.	Mandy Tipton (b) (4) (b) (4)	23 Sep 2020 14:02:38

US3692001
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:24:06
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User entered 'MRNA-1273 OR PLACEBO'	System	23 Sep 2020 14:02:38

US3692001
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:24:06

What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered '23 Sep 2020'	Mandy Tipton (b) (4) (b) (4)	23 Sep 2020 14:02:38

What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered '09:56'	Mandy Tipton (b) (4) (b) (4)	23 Sep 2020 14:02:38

FDA-CBER-2022-1614-3322313

Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User entered '23 Sep 2020 09:56'	System	23 Sep 2020 14:02:38

US3692001
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:24:06
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered 'Left Arm (LEFT ARM)'	Mandy Tipton (b) (4) (b) (4)	23 Sep 2020 14:02:38

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User entered 'ONCE'	System	23 Sep 2020 14:02:38

US3692001
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:24:06
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User entered 'INTRAMUSCULAR'	System	23 Sep 2020 14:02:38

US3692001

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:24:06

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:45:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 11:35:29

US3692001

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:24:06

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:45:25
User entered '23 Sep 2020'	(b) (4), (b) (6)	24 Sep 2020 11:35:29

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:45:25
User entered '09:06'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 11:35:29

US3692001

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:24:06

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User entered '23 Sep 2020 09:06'	System	24 Sep 2020 11:35:29

US3692001

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:24:06

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:45:25
User entered '23 Sep 2020'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 11:35:43

US3692001

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:24:06

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	24 Sep 2020 11:35:43

US3692001

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:24:06

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:45:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 11:35:43

Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:45:25
User entered '09:12'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 11:35:43

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User entered '23 Sep 2020 09:12'	System	24 Sep 2020 11:35:43

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	24 Sep 2020 11:35:43

FDA-CBER-2022-1614-3322327

US3692001

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:24:06

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:45:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 11:35:43

Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 09:24:06
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4)	13 Feb 2021 00:45:25
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 11:35:43

US3692001

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:24:06

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User entered empty.	System	24 Sep 2020 11:35:43

US3692001
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:24:06

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered 'Yes (Y)'	Mandy Tipton (b) (4) (b) (4)	23 Sep 2020 14:02:55

US3692001
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:24:06
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User entered '1'	System	23 Sep 2020 14:02:55

US3692001
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
Data entry locked.	System	23 Sep 2020 14:02:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Sep 2020 14:02:38

FDA-CBER-2022-1614-3322333

US3692001
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:24:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-23T10:28:48', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'd529c949-a7a8-4f26-aa8d-0219aa124b80'	System	23 Sep 2020 14:29:00
User entered 'Yes (Y)'	System	23 Sep 2020 14:29:00

US3692001
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:24:06

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-23T10:28:52', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'd529c949-a7a8-4f26-aa8d-0219aa124b80'	System	23 Sep 2020 14:29:00
User entered '98.0'	System	23 Sep 2020 14:29:00

US3692001

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:24:06

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-23T10:28:56', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'd529c949-a7a8-4f26-aa8d-0219aa124b80'	System	23 Sep 2020 14:29:00
User entered 'No (N)'	System	23 Sep 2020 14:29:00

US3692001
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:24:06
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-23T10:28:58', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'd529c949-a7a8-4f26-aa8d-0219aa124b80'	System	23 Sep 2020 14:29:00
User entered '23 Sep 2020 10:28'	System	23 Sep 2020 14:29:00

US3692001

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:24:06

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
User entered '23 Sep 2020 10:16'	System	23 Sep 2020 14:02:38

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
User entered '23 Sep 2020 12:46'	System	23 Sep 2020 14:02:38

FDA-CBER-2022-1614-3322339

US3692001
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
Data entry locked.	System	23 Sep 2020 14:02:38
User entered 'Day 1, after vaccination (at home)'	System	23 Sep 2020 14:02:38

US3692001
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:24:06
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-23T18:39:11', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '64ad2628-2228-44a0-8049-6222f892e960'	System	23 Sep 2020 22:39:26
User entered 'Yes (Y)'	System	23 Sep 2020 22:39:26

US3692001

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:24:06

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-23T18:39:18', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '64ad2628-2228-44a0-8049-6222f892e960'	System	23 Sep 2020 22:39:26
User entered '98.3'	System	23 Sep 2020 22:39:26

US3692001
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:24:06

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-23T18:39:21', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '64ad2628-2228-44a0-8049-6222f892e960'	System	23 Sep 2020 22:39:26
User entered 'No (N)'	System	23 Sep 2020 22:39:26

US3692001
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:24:06
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-23T18:39:24', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '64ad2628-2228-44a0-8049-6222f892e960'	System	23 Sep 2020 22:39:26
User entered '23 Sep 2020 18:39'	System	23 Sep 2020 22:39:26

US3692001
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:24:06
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
User entered '23 Sep 2020 13:41'	System	23 Sep 2020 14:02:38

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 14:02:38

US3692001
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
Data entry locked.	System	23 Sep 2020 14:02:38
User entered 'Day 2'	System	23 Sep 2020 14:02:38

US3692001

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:24:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-24T20:34:10', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '808910ea-9118-4c07-a4c7-7d82a6d227ff'	System	25 Sep 2020 00:34:24
User entered 'Yes (Y)'	System	25 Sep 2020 00:34:24

US3692001
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:24:06

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-24T20:34:15', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '808910ea-9118-4c07-a4c7-7d82a6d227ff'	System	25 Sep 2020 00:34:24
User entered '98.2'	System	25 Sep 2020 00:34:24

US3692001

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:24:06

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-24T20:34:17', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '808910ea-9118-4c07-a4c7-7d82a6d227ff'	System	25 Sep 2020 00:34:24
User entered 'No (N)'	System	25 Sep 2020 00:34:24

US3692001

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:24:06

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-24T20:34:20', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '808910ea-9118-4c07-a4c7-7d82a6d227ff'	System	25 Sep 2020 00:34:24
User entered '24 Sep 2020 20:34'	System	25 Sep 2020 00:34:24

US3692001

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:24:06

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 14:02:38

Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:24:06
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 14:02:38

US3692001
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
Data entry locked.	System	23 Sep 2020 14:02:38
User entered 'Day 3'	System	23 Sep 2020 14:02:38

US3692001
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:24:06
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-25T20:52:20', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '01de03b7-0ea3-40d6-8c39-509f14587781'	System	26 Sep 2020 00:52:32
User entered 'Yes (Y)'	System	26 Sep 2020 00:52:32

US3692001

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:24:06

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-25T20:52:23', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '01de03b7-0ea3-40d6-8c39-509f14587781'	System	26 Sep 2020 00:52:32
User entered '98.4'	System	26 Sep 2020 00:52:32

US3692001
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:24:06

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-25T20:52:27', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '01de03b7-0ea3-40d6-8c39-509f14587781'	System	26 Sep 2020 00:52:32
User entered 'No (N)'	System	26 Sep 2020 00:52:32

US3692001
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:24:06
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-25T20:52:30', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '01de03b7-0ea3-40d6-8c39-509f14587781'	System	26 Sep 2020 00:52:32
User entered '25 Sep 2020 20:52'	System	26 Sep 2020 00:52:32

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 14:02:38

US3692001

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:24:06

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 14:02:38

Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
Data entry locked.	System	23 Sep 2020 14:02:38
User entered 'Day 4'	System	23 Sep 2020 14:02:38

US3692001
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:24:06

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-26T20:59:42', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'e9e65e2e-95cd-44d7-98d8-d4b7fa6b0307'	System	27 Sep 2020 00:59:56
User entered 'Yes (Y)'	System	27 Sep 2020 00:59:56

US3692001
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:24:06

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-26T20:59:46', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'e9e65e2e-95cd-44d7-98d8-d4b7fa6b0307'	System	27 Sep 2020 00:59:56
User entered '98.3'	System	27 Sep 2020 00:59:56

US3692001

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:24:06

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-26T20:59:50', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'e9e65e2e-95cd-44d7-98d8-d4b7fa6b0307'	System	27 Sep 2020 00:59:56
User entered 'No (N)'	System	27 Sep 2020 00:59:56

US3692001

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:24:06

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-26T20:59:52', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'e9e65e2e-95cd-44d7-98d8-d4b7fa6b0307'	System	27 Sep 2020 00:59:56
User entered '26 Sep 2020 20:59'	System	27 Sep 2020 00:59:56

US3692001

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:24:06

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
User entered '26 Sep 2020 12:00'	System	23 Sep 2020 14:02:38

US3692001
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:24:06
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
User entered '27 Sep 2020 11:59'	System	23 Sep 2020 14:02:38

US3692001

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:24:06

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
Data entry locked.	System	23 Sep 2020 14:02:38
User entered 'Day 5'	System	23 Sep 2020 14:02:38

US3692001
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:24:06
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-27T20:22:42', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'b75a894c-5075-4151-a406-e413b62605a1'	System	28 Sep 2020 00:22:54
User entered 'Yes (Y)'	System	28 Sep 2020 00:22:54

US3692001
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:24:06

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-27T20:22:48', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'b75a894c-5075-4151-a406-e413b62605a1'	System	28 Sep 2020 00:22:54
User entered '98.3'	System	28 Sep 2020 00:22:54

US3692001
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:24:06

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-27T20:22:50', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'b75a894c-5075-4151-a406-e413b62605a1'	System	28 Sep 2020 00:22:54
User entered 'No (N)'	System	28 Sep 2020 00:22:54

US3692001

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:24:06

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-27T20:22:52', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'b75a894c-5075-4151-a406-e413b62605a1'	System	28 Sep 2020 00:22:54
User entered '27 Sep 2020 20:22'	System	28 Sep 2020 00:22:54

US3692001

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:24:06

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
User entered '27 Sep 2020 12:00'	System	23 Sep 2020 14:02:38

US3692001

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:24:06

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
User entered '28 Sep 2020 11:59'	System	23 Sep 2020 14:02:38

US3692001
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
Data entry locked.	System	23 Sep 2020 14:02:38
User entered 'Day 6'	System	23 Sep 2020 14:02:38

US3692001
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:24:06
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-28T21:10:21', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '442da92d-32c0-42c4-b17e-3d32f4f3be49'	System	29 Sep 2020 01:10:41
User entered 'Yes (Y)'	System	29 Sep 2020 01:10:41

US3692001
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:24:06

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-28T21:10:27', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '442da92d-32c0-42c4-b17e-3d32f4f3be49'	System	29 Sep 2020 01:10:41
User entered '98.5'	System	29 Sep 2020 01:10:41

US3692001

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:24:06

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-28T21:10:31', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '442da92d-32c0-42c4-b17e-3d32f4f3be49'	System	29 Sep 2020 01:10:41
User entered 'No (N)'	System	29 Sep 2020 01:10:41

US3692001
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:24:06
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-28T21:10:39', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '442da92d-32c0-42c4-b17e-3d32f4f3be49'	System	29 Sep 2020 01:10:41
User entered '28 Sep 2020 21:10'	System	29 Sep 2020 01:10:41

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
User entered '28 Sep 2020 12:00'	System	23 Sep 2020 14:02:38

FDA-CBER-2022-1614-3322380

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
User entered '29 Sep 2020 11:59'	System	23 Sep 2020 14:02:38

US3692001
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
Data entry locked.	System	23 Sep 2020 14:02:38
User entered 'Day 7'	System	23 Sep 2020 14:02:38

US3692001
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:24:06
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-29T12:00:23', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'f5cabe6d-8676-42d1-8658-27ff2c446a34'	System	29 Sep 2020 16:00:45
User entered 'Yes (Y)'	System	29 Sep 2020 16:00:45

US3692001
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:24:06

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-29T12:00:27', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'f5cabe6d-8676-42d1-8658-27ff2c446a34'	System	29 Sep 2020 16:00:45
User entered '97.7'	System	29 Sep 2020 16:00:45

US3692001

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:24:06

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-29T12:00:30', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'f5cabe6d-8676-42d1-8658-27ff2c446a34'	System	29 Sep 2020 16:00:45
User entered 'No (N)'	System	29 Sep 2020 16:00:45

US3692001
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:24:06
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-29T12:00:33', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'f5cabe6d-8676-42d1-8658-27ff2c446a34'	System	29 Sep 2020 16:00:45
User entered '29 Sep 2020 12:00'	System	29 Sep 2020 16:00:45

US3692001

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:24:06

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
User entered '29 Sep 2020 12:00'	System	23 Sep 2020 14:02:38

US3692001

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:24:06

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
User entered '30 Sep 2020 11:59'	System	23 Sep 2020 14:02:38

US3692001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
Data entry locked.	System	23 Sep 2020 14:02:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Sep 2020 14:02:38

US3692001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:24:06

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-23T10:29:03', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '1abaaa10-04f9-4d49-9762-60567bb9b73f'	System	23 Sep 2020 14:29:24
User entered 'None (1)'	System	23 Sep 2020 14:29:24

US3692001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:24:06
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-23T10:29:13', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '1abaaa10-04f9-4d49-9762-60567bb9b73f'	System	23 Sep 2020 14:29:24
User entered 'No (N)'	System	23 Sep 2020 14:29:24

US3692001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:24:06

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-23T10:29:16', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '1abaaa10-04f9-4d49-9762-60567bb9b73f'	System	23 Sep 2020 14:29:24
User entered 'No (N)'	System	23 Sep 2020 14:29:24

US3692001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:24:06

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-23T10:29:18', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '1abaaa10-04f9-4d49-9762-60567bb9b73f'	System	23 Sep 2020 14:29:24
User entered 'None (1)'	System	23 Sep 2020 14:29:24

US3692001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:24:06
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-23T10:29:21', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '1abaaa10-04f9-4d49-9762-60567bb9b73f'	System	23 Sep 2020 14:29:24
User entered '23 Sep 2020 10:29'	System	23 Sep 2020 14:29:24

US3692001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:24:06

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
User entered '23 Sep 2020 10:16'	System	23 Sep 2020 14:02:38

US3692001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:24:06

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
User entered '23 Sep 2020 12:46'	System	23 Sep 2020 14:02:38

US3692001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
Data entry locked.	System	23 Sep 2020 14:02:38
User entered 'Day 1, after vaccination (at home)'	System	23 Sep 2020 14:02:38

US3692001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:24:06

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-23T18:39:28', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '90d375f7-b332-4611-8bf0-c394740d81af'	System	23 Sep 2020 22:39:44
User entered 'None (1)'	System	23 Sep 2020 22:39:44

US3692001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:24:06
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-23T18:39:30', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '90d375f7-b332-4611-8bf0-c394740d81af'	System	23 Sep 2020 22:39:44
User entered 'No (N)'	System	23 Sep 2020 22:39:44

US3692001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:24:06
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-23T18:39:38', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '90d375f7-b332-4611-8bf0-c394740d81af'	System	23 Sep 2020 22:39:44
User entered 'No (N)'	System	23 Sep 2020 22:39:44

US3692001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:24:06

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-23T18:39:40', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '90d375f7-b332-4611-8bf0-c394740d81af'	System	23 Sep 2020 22:39:44
User entered 'None (1)'	System	23 Sep 2020 22:39:44

US3692001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:24:06
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-23T18:39:42', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '90d375f7-b332-4611-8bf0-c394740d81af'	System	23 Sep 2020 22:39:44
User entered '23 Sep 2020 18:39'	System	23 Sep 2020 22:39:44

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
User entered '23 Sep 2020 13:41'	System	23 Sep 2020 14:02:38

US3692001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:24:06
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 14:02:38

US3692001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
Data entry locked.	System	23 Sep 2020 14:02:38
User entered 'Day 2'	System	23 Sep 2020 14:02:38

US3692001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:24:06

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-24T20:34:23', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'c3d3579b-3277-4b9e-b8a6-786da6168593'	System	25 Sep 2020 00:34:37
User entered 'None (1)'	System	25 Sep 2020 00:34:37

US3692001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:24:06

Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-24T20:34:26', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'c3d3579b-3277-4b9e-b8a6-786da6168593'	System	25 Sep 2020 00:34:37
User entered 'No (N)'	System	25 Sep 2020 00:34:37

US3692001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:24:06

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-24T20:34:27', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'c3d3579b-3277-4b9e-b8a6-786da6168593'	System	25 Sep 2020 00:34:37
User entered 'No (N)'	System	25 Sep 2020 00:34:37

US3692001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:24:06

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-24T20:34:29', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'c3d3579b-3277-4b9e-b8a6-786da6168593'	System	25 Sep 2020 00:34:37
User entered 'None (1)'	System	25 Sep 2020 00:34:37

US3692001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:24:06
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-24T20:34:31', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'c3d3579b-3277-4b9e-b8a6-786da6168593'	System	25 Sep 2020 00:34:37
User entered '24 Sep 2020 20:34'	System	25 Sep 2020 00:34:37

US3692001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:24:06
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 14:02:38

US3692001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:24:06

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 14:02:38

US3692001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
Data entry locked.	System	23 Sep 2020 14:02:38
User entered 'Day 3'	System	23 Sep 2020 14:02:38

US3692001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:24:06

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-25T20:52:34', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'd4e7cf0d-4a50-45e9-9c3c-0d1ab598d7bb'	System	26 Sep 2020 00:52:45
User entered 'None (1)'	System	26 Sep 2020 00:52:45

US3692001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:24:06

Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-25T20:52:36', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'd4e7cf0d-4a50-45e9-9c3c-0d1ab598d7bb'	System	26 Sep 2020 00:52:45
User entered 'No (N)'	System	26 Sep 2020 00:52:45

US3692001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:24:06

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-25T20:52:38', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'd4e7cf0d-4a50-45e9-9c3c-0d1ab598d7bb'	System	26 Sep 2020 00:52:45
User entered 'No (N)'	System	26 Sep 2020 00:52:45

US3692001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:24:06

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-25T20:52:40', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'd4e7cf0d-4a50-45e9-9c3c-0d1ab598d7bb'	System	26 Sep 2020 00:52:45
User entered 'None (1)'	System	26 Sep 2020 00:52:45

US3692001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:24:06

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-25T20:52:43', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'd4e7cf0d-4a50-45e9-9c3c-0d1ab598d7bb'	System	26 Sep 2020 00:52:45
User entered '25 Sep 2020 20:52'	System	26 Sep 2020 00:52:45

US3692001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:24:06

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 14:02:38

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 14:02:38

US3692001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
Data entry locked.	System	23 Sep 2020 14:02:38
User entered 'Day 4'	System	23 Sep 2020 14:02:38

US3692001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:24:06

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-26T20:59:56', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'f6e4f14d-cab3-4823-9e4f-7c6861aeb266'	System	27 Sep 2020 01:00:09
User entered 'None (1)'	System	27 Sep 2020 01:00:09

US3692001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:24:06
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-26T20:59:58', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'f6e4f14d-cab3-4823-9e4f-7c6861aeb266'	System	27 Sep 2020 01:00:09
User entered 'No (N)'	System	27 Sep 2020 01:00:09

US3692001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:24:06
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-26T21:00:00', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'f6e4f14d-cab3-4823-9e4f-7c6861aeb266'	System	27 Sep 2020 01:00:09
User entered 'No (N)'	System	27 Sep 2020 01:00:09

US3692001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:24:06

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-26T21:00:02', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'f6e4f14d-cab3-4823-9e4f-7c6861aeb266'	System	27 Sep 2020 01:00:09
User entered 'None (1)'	System	27 Sep 2020 01:00:09

US3692001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:24:06
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-26T21:00:05', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'f6e4f14d-cab3-4823-9e4f-7c6861aeb266'	System	27 Sep 2020 01:00:09
User entered '26 Sep 2020 21:00'	System	27 Sep 2020 01:00:09

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
User entered '26 Sep 2020 12:00'	System	23 Sep 2020 14:02:38

FDA-CBER-2022-1614-3322427

US3692001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:24:06

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
User entered '27 Sep 2020 11:59'	System	23 Sep 2020 14:02:38

FDA-CBER-2022-1614-3322428

US3692001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
Data entry locked.	System	23 Sep 2020 14:02:38
User entered 'Day 5'	System	23 Sep 2020 14:02:38

US3692001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:24:06

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-27T20:22:56', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'bf1f60bd-489f-406f-9be0-0cb6874f75d9'	System	28 Sep 2020 00:23:05
User entered 'None (1)'	System	28 Sep 2020 00:23:05

US3692001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:24:06
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-27T20:22:58', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'bf1f60bd-489f-406f-9be0-0cb6874f75d9'	System	28 Sep 2020 00:23:05
User entered 'No (N)'	System	28 Sep 2020 00:23:05

US3692001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:24:06
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-27T20:23:00', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'bf1f60bd-489f-406f-9be0-0cb6874f75d9'	System	28 Sep 2020 00:23:05
User entered 'No (N)'	System	28 Sep 2020 00:23:05

US3692001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:24:06

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-27T20:23:02', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'bf1f60bd-489f-406f-9be0-0cb6874f75d9'	System	28 Sep 2020 00:23:05
User entered 'None (1)'	System	28 Sep 2020 00:23:05

US3692001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:24:06
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-27T20:23:04', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'bf1f60bd-489f-406f-9be0-0cb6874f75d9'	System	28 Sep 2020 00:23:05
User entered '27 Sep 2020 20:23'	System	28 Sep 2020 00:23:05

US3692001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:24:06
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
User entered '27 Sep 2020 12:00'	System	23 Sep 2020 14:02:38

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
User entered '28 Sep 2020 11:59'	System	23 Sep 2020 14:02:38

US3692001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
Data entry locked.	System	23 Sep 2020 14:02:38
User entered 'Day 6'	System	23 Sep 2020 14:02:38

US3692001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:24:06

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-28T21:10:48', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '50ef3c10-8993-4423-82a6-507005832221'	System	29 Sep 2020 01:10:56
User entered 'None (1)'	System	29 Sep 2020 01:10:56

US3692001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:24:06

Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-28T21:10:46', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '50ef3c10-8993-4423-82a6-507005832221'	System	29 Sep 2020 01:10:56
User entered 'No (N)'	System	29 Sep 2020 01:10:56

US3692001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:24:06
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-28T21:10:49', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '50ef3c10-8993-4423-82a6-507005832221'	System	29 Sep 2020 01:10:56
User entered 'No (N)'	System	29 Sep 2020 01:10:56

US3692001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:24:06

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-28T21:10:50', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '50ef3c10-8993-4423-82a6-507005832221'	System	29 Sep 2020 01:10:56
User entered 'None (1)'	System	29 Sep 2020 01:10:56

US3692001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:24:06
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-28T21:10:53', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '50ef3c10-8993-4423-82a6-507005832221'	System	29 Sep 2020 01:10:56
User entered '28 Sep 2020 21:10'	System	29 Sep 2020 01:10:56

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
User entered '28 Sep 2020 12:00'	System	23 Sep 2020 14:02:38

FDA-CBER-2022-1614-3322443

US3692001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:24:06
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
User entered '29 Sep 2020 11:59'	System	23 Sep 2020 14:02:38

US3692001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
Data entry locked.	System	23 Sep 2020 14:02:38
User entered 'Day 7'	System	23 Sep 2020 14:02:38

US3692001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:24:06

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-29T12:00:36', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'f0baa3cf-368d-42af-9d4c-c16f48a22599'	System	29 Sep 2020 16:00:57
User entered 'None (1)'	System	29 Sep 2020 16:00:57

US3692001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:24:06

Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-29T12:00:39', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'f0baa3cf-368d-42af-9d4c-c16f48a22599'	System	29 Sep 2020 16:00:57
User entered 'No (N)'	System	29 Sep 2020 16:00:57

US3692001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:24:06
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-29T12:00:40', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'f0baa3cf-368d-42af-9d4c-c16f48a22599'	System	29 Sep 2020 16:00:57
User entered 'No (N)'	System	29 Sep 2020 16:00:57

US3692001

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:24:06

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-29T12:00:41', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'f0baa3cf-368d-42af-9d4c-c16f48a22599'	System	29 Sep 2020 16:00:57
User entered 'None (1)'	System	29 Sep 2020 16:00:57

US3692001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:24:06
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-29T12:00:44', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'f0baa3cf-368d-42af-9d4c-c16f48a22599'	System	29 Sep 2020 16:00:57
User entered '29 Sep 2020 12:00'	System	29 Sep 2020 16:00:57

Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:24:06
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
User entered '29 Sep 2020 12:00'	System	23 Sep 2020 14:02:38

US3692001
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:24:06
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
User entered '30 Sep 2020 11:59'	System	23 Sep 2020 14:02:38

US3692001
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
Data entry locked.	System	23 Sep 2020 14:02:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Sep 2020 14:02:38

US3692001
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:24:06
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-23T10:29:25', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'dd5dbc12-9765-41bc-8c24-79b7f18a4d3f'	System	23 Sep 2020 14:29:51
User entered 'None (0)'	System	23 Sep 2020 14:29:51

US3692001
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:24:06
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-23T10:29:27', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'dd5dbc12-9765-41bc-8c24-79b7f18a4d3f'	System	23 Sep 2020 14:29:51
User entered 'None (0)'	System	23 Sep 2020 14:29:51

US3692001
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:24:06
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-23T10:29:29', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'dd5dbc12-9765-41bc-8c24-79b7f18a4d3f'	System	23 Sep 2020 14:29:51
User entered 'None (0)'	System	23 Sep 2020 14:29:51

US3692001
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:24:06
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-23T10:29:31', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'dd5dbc12-9765-41bc-8c24-79b7f18a4d3f'	System	23 Sep 2020 14:29:51
User entered 'None (0)'	System	23 Sep 2020 14:29:51

US3692001
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:24:06
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-23T10:29:33', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'dd5dbc12-9765-41bc-8c24-79b7f18a4d3f'	System	23 Sep 2020 14:29:51
User entered 'None (0)'	System	23 Sep 2020 14:29:51

US3692001
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:24:06
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-23T10:29:36', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'dd5dbc12-9765-41bc-8c24-79b7f18a4d3f'	System	23 Sep 2020 14:29:51
User entered 'None (0)'	System	23 Sep 2020 14:29:51

FDA-CBER-2022-1614-3322459

US3692001

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:24:06

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-23T10:29:41', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'dd5dbc12-9765-41bc-8c24-79b7f18a4d3f'	System	23 Sep 2020 14:29:51
User entered 'No (N)'	System	23 Sep 2020 14:29:51

US3692001
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:24:06
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-23T10:29:48', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'dd5dbc12-9765-41bc-8c24-79b7f18a4d3f'	System	23 Sep 2020 14:29:51
User entered '23 Sep 2020 10:29'	System	23 Sep 2020 14:29:51

US3692001

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:24:06

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
User entered '23 Sep 2020 10:16'	System	23 Sep 2020 14:02:38

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
User entered '23 Sep 2020 12:46'	System	23 Sep 2020 14:02:38

FDA-CBER-2022-1614-3322463

US3692001
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
Data entry locked.	System	23 Sep 2020 14:02:38
User entered 'Day 1, after vaccination (at home)'	System	23 Sep 2020 14:02:38

US3692001
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:24:06
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-23T18:39:46', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '2f4d313e-683f-4cbf-9d66-737ca7ed9fda'	System	23 Sep 2020 22:40:05
User entered 'None (0)'	System	23 Sep 2020 22:40:05

US3692001
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:24:06
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-23T18:39:48', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '2f4d313e-683f-4cbf-9d66-737ca7ed9fda'	System	23 Sep 2020 22:40:05
User entered 'None (0)'	System	23 Sep 2020 22:40:05

US3692001
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:24:06
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-23T18:39:49', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '2f4d313e-683f-4cbf-9d66-737ca7ed9fda'	System	23 Sep 2020 22:40:05
User entered 'None (0)'	System	23 Sep 2020 22:40:05

US3692001
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:24:06
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-23T18:39:52', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '2f4d313e-683f-4cbf-9d66-737ca7ed9fda'	System	23 Sep 2020 22:40:05
User entered 'None (0)'	System	23 Sep 2020 22:40:05

US3692001
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:24:06
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-23T18:39:54', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '2f4d313e-683f-4cbf-9d66-737ca7ed9fda'	System	23 Sep 2020 22:40:05
User entered 'None (0)'	System	23 Sep 2020 22:40:05

US3692001
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:24:06
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-23T18:39:55', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '2f4d313e-683f-4cbf-9d66-737ca7ed9fda'	System	23 Sep 2020 22:40:05
User entered 'None (0)'	System	23 Sep 2020 22:40:05

US3692001

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:24:06

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-23T18:39:57', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '2f4d313e-683f-4cbf-9d66-737ca7ed9fda'	System	23 Sep 2020 22:40:05
User entered 'No (N)'	System	23 Sep 2020 22:40:05

US3692001

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:24:06

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-23T18:40:00', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '2f4d313e-683f-4cbf-9d66-737ca7ed9fda'	System	23 Sep 2020 22:40:05
User entered '23 Sep 2020 18:40'	System	23 Sep 2020 22:40:05

US3692001

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:24:06

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
User entered '23 Sep 2020 13:41'	System	23 Sep 2020 14:02:38

US3692001

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:24:06

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 14:02:38

US3692001
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
Data entry locked.	System	23 Sep 2020 14:02:38
User entered 'Day 2'	System	23 Sep 2020 14:02:38

US3692001
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:24:06
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-24T20:34:34', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'c7d90a5a-1528-4be2-8b42-bc89600bd349'	System	25 Sep 2020 00:34:53
User entered 'None (0)'	System	25 Sep 2020 00:34:53

US3692001
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:24:06
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-24T20:34:36', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'c7d90a5a-1528-4be2-8b42-bc89600bd349'	System	25 Sep 2020 00:34:53
User entered 'None (0)'	System	25 Sep 2020 00:34:53

US3692001
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:24:06
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-24T20:34:37', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'c7d90a5a-1528-4be2-8b42-bc89600bd349'	System	25 Sep 2020 00:34:53
User entered 'None (0)'	System	25 Sep 2020 00:34:53

US3692001
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:24:06
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-24T20:34:39', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'c7d90a5a-1528-4be2-8b42-bc89600bd349'	System	25 Sep 2020 00:34:53
User entered 'None (0)'	System	25 Sep 2020 00:34:53

US3692001
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:24:06
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-24T20:34:44', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'c7d90a5a-1528-4be2-8b42-bc89600bd349'	System	25 Sep 2020 00:34:53
User entered 'None (0)'	System	25 Sep 2020 00:34:53

US3692001
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:24:06
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-24T20:34:46', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'c7d90a5a-1528-4be2-8b42-bc89600bd349'	System	25 Sep 2020 00:34:53
User entered 'None (0)'	System	25 Sep 2020 00:34:53

US3692001

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:24:06

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-24T20:34:48', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'c7d90a5a-1528-4be2-8b42-bc89600bd349'	System	25 Sep 2020 00:34:53
User entered 'No (N)'	System	25 Sep 2020 00:34:53

US3692001

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:24:06

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-24T20:34:51', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'c7d90a5a-1528-4be2-8b42-bc89600bd349'	System	25 Sep 2020 00:34:53
User entered '24 Sep 2020 20:34'	System	25 Sep 2020 00:34:53

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 14:02:38

US3692001
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:24:06
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 14:02:38

US3692001
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
Data entry locked.	System	23 Sep 2020 14:02:38
User entered 'Day 3'	System	23 Sep 2020 14:02:38

US3692001
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:24:06
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-25T20:52:46', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'c6d81065-4f91-490b-8356-919c9628d3d8'	System	26 Sep 2020 00:53:00
User entered 'None (0)'	System	26 Sep 2020 00:53:00

US3692001
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:24:06
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-25T20:52:47', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'c6d81065-4f91-490b-8356-919c9628d3d8'	System	26 Sep 2020 00:53:00
User entered 'None (0)'	System	26 Sep 2020 00:53:00

US3692001
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:24:06
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-25T20:52:49', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'c6d81065-4f91-490b-8356-919c9628d3d8'	System	26 Sep 2020 00:53:00
User entered 'None (0)'	System	26 Sep 2020 00:53:00

US3692001
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:24:06
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-25T20:52:50', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'c6d81065-4f91-490b-8356-919c9628d3d8'	System	26 Sep 2020 00:53:00
User entered 'None (0)'	System	26 Sep 2020 00:53:00

US3692001
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:24:06
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-25T20:52:52', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'c6d81065-4f91-490b-8356-919c9628d3d8'	System	26 Sep 2020 00:53:00
User entered 'None (0)'	System	26 Sep 2020 00:53:00

US3692001
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:24:06
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-25T20:52:53', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'c6d81065-4f91-490b-8356-919c9628d3d8'	System	26 Sep 2020 00:53:00
User entered 'None (0)'	System	26 Sep 2020 00:53:00

US3692001
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:24:06

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-25T20:52:54', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'c6d81065-4f91-490b-8356-919c9628d3d8'	System	26 Sep 2020 00:53:00
User entered 'No (N)'	System	26 Sep 2020 00:53:00

US3692001
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:24:06
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-25T20:52:56', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'c6d81065-4f91-490b-8356-919c9628d3d8'	System	26 Sep 2020 00:53:00
User entered '25 Sep 2020 20:52'	System	26 Sep 2020 00:53:00

US3692001

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:24:06

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 14:02:38

US3692001

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:24:06

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 14:02:38

US3692001
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
Data entry locked.	System	23 Sep 2020 14:02:38
User entered 'Day 4'	System	23 Sep 2020 14:02:38

US3692001
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:24:06
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-26T21:00:08', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '2d5ee84c-3d26-4d0f-a815-e56b30dcbab8'	System	27 Sep 2020 01:00:21
User entered 'None (0)'	System	27 Sep 2020 01:00:21

US3692001
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:24:06
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-26T21:00:09', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '2d5ee84c-3d26-4d0f-a815-e56b30dcbab8'	System	27 Sep 2020 01:00:21
User entered 'None (0)'	System	27 Sep 2020 01:00:21

US3692001
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:24:06
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-26T21:00:11', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '2d5ee84c-3d26-4d0f-a815-e56b30dcbab8'	System	27 Sep 2020 01:00:21
User entered 'None (0)'	System	27 Sep 2020 01:00:21

US3692001
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:24:06
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-26T21:00:12', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '2d5ee84c-3d26-4d0f-a815-e56b30dcbab8'	System	27 Sep 2020 01:00:21
User entered 'None (0)'	System	27 Sep 2020 01:00:21

US3692001
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:24:06
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-26T21:00:13', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '2d5ee84c-3d26-4d0f-a815-e56b30dcbab8'	System	27 Sep 2020 01:00:21
User entered 'None (0)'	System	27 Sep 2020 01:00:21

US3692001
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:24:06
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-26T21:00:14', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '2d5ee84c-3d26-4d0f-a815-e56b30dcbab8'	System	27 Sep 2020 01:00:21
User entered 'None (0)'	System	27 Sep 2020 01:00:21

US3692001

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:24:06

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-26T21:00:16', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '2d5ee84c-3d26-4d0f-a815-e56b30dcbab8'	System	27 Sep 2020 01:00:21
User entered 'No (N)'	System	27 Sep 2020 01:00:21

US3692001

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:24:06

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-26T21:00:18', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '2d5ee84c-3d26-4d0f-a815-e56b30dcbab8'	System	27 Sep 2020 01:00:21
User entered '26 Sep 2020 21:00'	System	27 Sep 2020 01:00:21

US3692001

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:24:06

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
User entered '26 Sep 2020 12:00'	System	23 Sep 2020 14:02:38

US3692001
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:24:06
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
User entered '27 Sep 2020 11:59'	System	23 Sep 2020 14:02:38

US3692001
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
Data entry locked.	System	23 Sep 2020 14:02:38
User entered 'Day 5'	System	23 Sep 2020 14:02:38

US3692001
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:24:06
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-27T20:23:07', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '9daf6f37-fcf5-414f-9801-4e3d72bb4179'	System	28 Sep 2020 00:23:21
User entered 'None (0)'	System	28 Sep 2020 00:23:21

US3692001
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:24:06
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-27T20:23:09', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '9daf6f37-fcf5-414f-9801-4e3d72bb4179'	System	28 Sep 2020 00:23:21
User entered 'None (0)'	System	28 Sep 2020 00:23:21

US3692001
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:24:06
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-27T20:23:10', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '9daf6f37-fcf5-414f-9801-4e3d72bb4179'	System	28 Sep 2020 00:23:21
User entered 'None (0)'	System	28 Sep 2020 00:23:21

US3692001
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:24:06
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-27T20:23:11', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '9daf6f37-fcf5-414f-9801-4e3d72bb4179'	System	28 Sep 2020 00:23:21
User entered 'None (0)'	System	28 Sep 2020 00:23:21

US3692001
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:24:06
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-27T20:23:12', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '9daf6f37-fcf5-414f-9801-4e3d72bb4179'	System	28 Sep 2020 00:23:21
User entered 'None (0)'	System	28 Sep 2020 00:23:21

US3692001
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:24:06
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-27T20:23:14', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '9daf6f37-fcf5-414f-9801-4e3d72bb4179'	System	28 Sep 2020 00:23:21
User entered 'None (0)'	System	28 Sep 2020 00:23:21

US3692001

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:24:06

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-27T20:23:15', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '9daf6f37-fcf5-414f-9801-4e3d72bb4179'	System	28 Sep 2020 00:23:21
User entered 'No (N)'	System	28 Sep 2020 00:23:21

US3692001

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:24:06

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-27T20:23:17', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '9daf6f37-fcf5-414f-9801-4e3d72bb4179'	System	28 Sep 2020 00:23:21
User entered '27 Sep 2020 20:23'	System	28 Sep 2020 00:23:21

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
User entered '27 Sep 2020 12:00'	System	23 Sep 2020 14:02:38

FDA-CBER-2022-1614-3322517

US3692001

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:24:06

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
User entered '28 Sep 2020 11:59'	System	23 Sep 2020 14:02:38

US3692001
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
Data entry locked.	System	23 Sep 2020 14:02:38
User entered 'Day 6'	System	23 Sep 2020 14:02:38

US3692001
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:24:06
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-28T21:10:57', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'e1c8a1c4-f4d0-4f87-9851-5269f72e2151'	System	29 Sep 2020 01:11:09
User entered 'None (0)'	System	29 Sep 2020 01:11:09

US3692001
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:24:06
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-28T21:10:58', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'e1c8a1c4-f4d0-4f87-9851-5269f72e2151'	System	29 Sep 2020 01:11:09
User entered 'None (0)'	System	29 Sep 2020 01:11:09

FDA-CBER-2022-1614-3322521

US3692001
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:24:06
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-28T21:11:00', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'e1c8a1c4-f4d0-4f87-9851-5269f72e2151'	System	29 Sep 2020 01:11:09
User entered 'None (0)'	System	29 Sep 2020 01:11:09

US3692001
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:24:06
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-28T21:11:01', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'e1c8a1c4-f4d0-4f87-9851-5269f72e2151'	System	29 Sep 2020 01:11:09
User entered 'None (0)'	System	29 Sep 2020 01:11:09

US3692001
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:24:06
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-28T21:11:02', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'e1c8a1c4-f4d0-4f87-9851-5269f72e2151'	System	29 Sep 2020 01:11:09
User entered 'None (0)'	System	29 Sep 2020 01:11:09

US3692001
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:24:06
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-28T21:11:03', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'e1c8a1c4-f4d0-4f87-9851-5269f72e2151'	System	29 Sep 2020 01:11:09
User entered 'None (0)'	System	29 Sep 2020 01:11:09

US3692001

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:24:06

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-28T21:11:04', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'e1c8a1c4-f4d0-4f87-9851-5269f72e2151'	System	29 Sep 2020 01:11:09
User entered 'No (N)'	System	29 Sep 2020 01:11:09

US3692001
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:24:06
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-28T21:11:07', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'e1c8a1c4-f4d0-4f87-9851-5269f72e2151'	System	29 Sep 2020 01:11:09
User entered '28 Sep 2020 21:11'	System	29 Sep 2020 01:11:09

US3692001
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:24:06
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
User entered '28 Sep 2020 12:00'	System	23 Sep 2020 14:02:38

US3692001
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:24:06
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
User entered '29 Sep 2020 11:59'	System	23 Sep 2020 14:02:38

US3692001
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
Data entry locked.	System	23 Sep 2020 14:02:38
User entered 'Day 7'	System	23 Sep 2020 14:02:38

US3692001
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:24:06
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-29T12:00:47', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'd9feba13-4725-4100-a208-371936883861'	System	29 Sep 2020 16:01:21
User entered 'None (0)'	System	29 Sep 2020 16:01:21

US3692001
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:24:06
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-29T12:00:49', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'd9feba13-4725-4100-a208-371936883861'	System	29 Sep 2020 16:01:21
User entered 'None (0)'	System	29 Sep 2020 16:01:21

US3692001
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:24:06

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-29T12:00:50', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'd9feba13-4725-4100-a208-371936883861'	System	29 Sep 2020 16:01:21
User entered 'None (0)'	System	29 Sep 2020 16:01:21

US3692001
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:24:06
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-29T12:00:51', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'd9feba13-4725-4100-a208-371936883861'	System	29 Sep 2020 16:01:21
User entered 'None (0)'	System	29 Sep 2020 16:01:21

US3692001
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:24:06
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-29T12:00:52', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'd9feba13-4725-4100-a208-371936883861'	System	29 Sep 2020 16:01:21
User entered 'None (0)'	System	29 Sep 2020 16:01:21

US3692001
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:24:06
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-29T12:00:54', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'd9feba13-4725-4100-a208-371936883861'	System	29 Sep 2020 16:01:21
User entered 'None (0)'	System	29 Sep 2020 16:01:21

US3692001
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:24:06

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-29T12:00:56', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'd9feba13-4725-4100-a208-371936883861'	System	29 Sep 2020 16:01:21
User entered 'No (N)'	System	29 Sep 2020 16:01:21

US3692001
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:24:06
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-09-29T12:00:58', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'd9feba13-4725-4100-a208-371936883861'	System	29 Sep 2020 16:01:21
User entered '29 Sep 2020 12:00'	System	29 Sep 2020 16:01:21

US3692001

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:24:06

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
User entered '29 Sep 2020 12:00'	System	23 Sep 2020 14:02:38

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
User entered '30 Sep 2020 11:59'	System	23 Sep 2020 14:02:38

FDA-CBER-2022-1614-3322540

US3692001
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:24:06

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered 'Yes (Y)'	Alexander Bradley (b) (4) (b) (4)	30 Sep 2020 12:30:38

US3692001

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:06

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered '30 Sep 2020'	Alexander Bradley (b) (4) (b) (4)	30 Sep 2020 12:30:38

US3692001
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:24:06
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered 'Contact Made (CONTACT MADE)'	Alexander Bradley (b) (4) (b) (4)	30 Sep 2020 12:30:38

US3692001

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:06

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered 'no ae or covid symptoms reported on ediary. participant reports no health changes.' reason for change: Data Entry Error	Abigail Riddick (b) (4) (b) (4)	09 Oct 2020 19:24:40
User entered empty.	Alexander Bradley (b) (4) (b) (4)	30 Sep 2020 12:30:38

US3692001
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:24:06

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered 'Yes (Y)'	Alexander Bradley (b) (4) (b) (4)	30 Sep 2020 12:30:41

US3692001
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:24:06
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User entered '1'	System	30 Sep 2020 12:30:41

US3692001

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:06

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered 'Yes (Y)'	Patti Vasquez (b) (4) (b) (4)	07 Oct 2020 13:59:41

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered '07 Oct 2020'	Patti Vasquez (b) (4) (b) (4)	07 Oct 2020 13:59:41

US3692001

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:06

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered 'Contact Made (CONTACT MADE)'	Patti Vasquez (b) (4) (b) (4)	07 Oct 2020 13:59:41

US3692001
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:24:06
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered 'Participant reports no changes since last study contact.'	Patti Vasquez (b) (4) (b) (4)	07 Oct 2020 13:59:41

US3692001

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:24:06

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered 'Yes (Y)'	Patti Vasquez (b) (4) (b) (4)	07 Oct 2020 13:59:47

US3692001
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:24:06
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User entered '1'	System	07 Oct 2020 13:59:47

US3692001
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:24:06

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered 'Yes (Y)'	Patti Vasquez (b) (4) (b) (4)	15 Oct 2020 12:29:08

US3692001
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:24:06

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered '15 Oct 2020'	Patti Vasquez (b) (4) (b) (4)	15 Oct 2020 12:29:08

US3692001
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:24:06
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered 'Contact Made (CONTACT MADE)'	Patti Vasquez (b) (4) (b) (4)	15 Oct 2020 12:29:08

US3692001
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:24:06
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered empty.	Patti Vasquez (b) (4) (b) (4)	15 Oct 2020 12:29:08

US3692001
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:24:06

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered 'Yes (Y)'	Patti Vasquez (b) (4) (b) (4)	15 Oct 2020 12:29:15

US3692001
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:24:06
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User entered '1'	System	15 Oct 2020 12:29:15

US3692001
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:24:06
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered 'Yes (Y)'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 22:48:45

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered '23 Oct 2020'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 22:48:45

FDA-CBER-2022-1614-3322560

US3692001
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:24:06

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered 'Clinic (Clinic)'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 22:48:45

US3692001
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:24:06
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User entered 'VISIT3'	System	23 Oct 2020 22:48:45

US3692001
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:06
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered 'Yes (Y)'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 22:49:33

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered '23 Oct 2020'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 22:49:33

FDA-CBER-2022-1614-3322564

US3692001
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:06

Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered '8:30'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 22:49:33

US3692001

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:06

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User entered '23 Oct 2020 8:30'	System	23 Oct 2020 22:49:33

US3692001
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:06
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered '36.4' C	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 22:49:33

US3692001
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:06

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered 'Oral (Oral)'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 22:49:33

US3692001
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:06
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered empty.	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 22:49:33

US3692001
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:06
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered '69'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 22:49:33

US3692001
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:06
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User entered 'bpm'	System	23 Oct 2020 22:49:33

US3692001
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:06
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered '12'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 22:49:33

FDA-CBER-2022-1614-3322572

US3692001
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:06

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User entered 'breaths/min'	System	23 Oct 2020 22:49:33

FDA-CBER-2022-1614-3322573

US3692001
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:06
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered '110'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 22:49:33

US3692001
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:06
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User entered 'mmHg'	System	23 Oct 2020 22:49:33

US3692001

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:06

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered '69'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 22:49:33

US3692001
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:06
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User entered 'mmHg'	System	23 Oct 2020 22:49:33

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07

Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Generated On: 10 Jun 2021 09:24:06
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered 'No (N)'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 22:50:02

US3692001

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:24:06

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered empty.	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 22:50:02

US3692001

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:24:06

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered 'Yes (Y)'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 22:50:23

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered '23 Oct 2020'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 22:50:23

FDA-CBER-2022-1614-3322583

US3692001

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:24:06

Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered '8:48'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 22:50:23

US3692001

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:24:06

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User entered '23 Oct 2020 8:48'	System	23 Oct 2020 22:50:23

US3692001
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:24:06

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	13 Feb 2021 00:45:25
User entered 'Yes (Y)'	Kristi Kirkland (b) (4) (b) (4)	23 Oct 2020 22:50:27

US3692001
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:24:06
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User entered '1'	System	23 Oct 2020 22:50:27

US3692001
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
Data entry locked.	System	26 Aug 2020 21:37:17
User entered 'Day 64'	System	26 Aug 2020 21:37:17

US3692001

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-10-26T08:21:46', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'ec921e66-147e-470c-9d88-a9a358f9df7e'	System	26 Oct 2020 12:21:56
User entered 'No (N)'	System	26 Oct 2020 12:21:56

US3692001
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-10-26T08:21:48', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'ec921e66-147e-470c-9d88-a9a358f9df7e'	System	26 Oct 2020 12:21:56
User entered 'No (N)'	System	26 Oct 2020 12:21:56

FDA-CBER-2022-1614-3322590

US3692001
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-10-26T08:21:52', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'ec921e66-147e-470c-9d88-a9a358f9df7e'	System	26 Oct 2020 12:21:56
User entered '26 Oct 2020 08:21:52'	System	26 Oct 2020 12:21:56

US3692001

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
Data entry locked.	System	26 Aug 2020 21:37:17
User entered '26 Oct 2020 00:01'	System	26 Aug 2020 21:37:17

US3692001
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
Data entry locked.	System	26 Aug 2020 21:37:17
User entered '30 Oct 2020 23:59'	System	26 Aug 2020 21:37:17

US3692001
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
Data entry locked.	System	26 Aug 2020 21:37:17
User entered 'Day 71'	System	26 Aug 2020 21:37:17

US3692001

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-11-02T08:52:33', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '21cb9a0e-a901-424b-974e-c4072f89a544'	System	02 Nov 2020 13:52:43
User entered 'No (N)'	System	02 Nov 2020 13:52:43

US3692001

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-11-02T08:52:36', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '21cb9a0e-a901-424b-974e-c4072f89a544'	System	02 Nov 2020 13:52:43
User entered 'No (N)'	System	02 Nov 2020 13:52:43

US3692001

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-11-02T08:52:40', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '21cb9a0e-a901-424b-974e-c4072f89a544'	System	02 Nov 2020 13:52:43
User entered '02 Nov 2020 08:52:40'	System	02 Nov 2020 13:52:43

FDA-CBER-2022-1614-3322597

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
Data entry locked.	System	26 Aug 2020 21:37:17
User entered '02 Nov 2020 00:01'	System	26 Aug 2020 21:37:17

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
Data entry locked.	System	26 Aug 2020 21:37:17
User entered '06 Nov 2020 23:59'	System	26 Aug 2020 21:37:17

FDA-CBER-2022-1614-3322599

US3692001
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
Data entry locked.	System	26 Aug 2020 21:37:17
User entered 'Day 78'	System	26 Aug 2020 21:37:17

US3692001

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-11-09T10:04:20', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '433342db-4100-466a-ae44-b3ee59ab1008'	System	09 Nov 2020 15:04:30
User entered 'No (N)'	System	09 Nov 2020 15:04:30

US3692001

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-11-09T10:04:23', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '433342db-4100-466a-ae44-b3ee59ab1008'	System	09 Nov 2020 15:04:30
User entered 'No (N)'	System	09 Nov 2020 15:04:30

US3692001

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-11-09T10:04:26', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '433342db-4100-466a-ae44-b3ee59ab1008'	System	09 Nov 2020 15:04:30
User entered '09 Nov 2020 10:04:26'	System	09 Nov 2020 15:04:30

US3692001
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
Data entry locked.	System	26 Aug 2020 21:37:17
User entered '09 Nov 2020 00:01'	System	26 Aug 2020 21:37:17

US3692001
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:18:16
Data entry locked.	System	26 Aug 2020 21:37:17
User entered '13 Nov 2020 23:59'	System	26 Aug 2020 21:37:17

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 18:23:18

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-11-23T07:40:11', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '400ffe41-f389-409c-821d-2e18095c373e'	System	23 Nov 2020 12:40:23
User entered 'No (N)'	System	23 Nov 2020 12:40:23

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-11-23T07:40:14', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '400ffe41-f389-409c-821d-2e18095c373e'	System	23 Nov 2020 12:40:23
User entered 'No (N)'	System	23 Nov 2020 12:40:23

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-11-23T07:40:22', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '400ffe41-f389-409c-821d-2e18095c373e'	System	23 Nov 2020 12:40:23
User entered '23 Nov 2020 07:40:22'	System	23 Nov 2020 12:40:23

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '20 Nov 2020 00:01'	System	19 Nov 2020 18:23:18

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '24 Nov 2020 23:59'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 18:23:18

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-12-01T19:25:03', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '26b00001-23c9-4f12-a3ce-36f8d6ce52eb'	System	02 Dec 2020 00:25:12
User entered 'No (N)'	System	02 Dec 2020 00:25:12

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-12-01T19:25:07', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '26b00001-23c9-4f12-a3ce-36f8d6ce52eb'	System	02 Dec 2020 00:25:12
User entered 'No (N)'	System	02 Dec 2020 00:25:12

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-12-01T19:25:11', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '26b00001-23c9-4f12-a3ce-36f8d6ce52eb'	System	02 Dec 2020 00:25:12
User entered '01 Dec 2020 19:25:11'	System	02 Dec 2020 00:25:12

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '27 Nov 2020 00:01'	System	19 Nov 2020 18:23:18

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '01 Dec 2020 23:59'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 18:23:18

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-12-04T15:58:24', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'ed4e9f3b-75b7-471d-90a1-99afcb6b0988'	System	04 Dec 2020 20:58:32
User entered 'No (N)'	System	04 Dec 2020 20:58:32

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-12-04T15:58:27', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'ed4e9f3b-75b7-471d-90a1-99afcb6b0988'	System	04 Dec 2020 20:58:32
User entered 'No (N)'	System	04 Dec 2020 20:58:32

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-12-04T15:58:30', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'ed4e9f3b-75b7-471d-90a1-99afcb6b0988'	System	04 Dec 2020 20:58:32
User entered '04 Dec 2020 15:58:30'	System	04 Dec 2020 20:58:32

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '04 Dec 2020 00:01'	System	19 Nov 2020 18:23:18

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '08 Dec 2020 23:59'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 18:23:18

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-12-13T13:27:27', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '75e48d1f-a9de-488d-90e0-ef45502a54cc'	System	13 Dec 2020 18:27:37
User entered 'No (N)'	System	13 Dec 2020 18:27:37

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-12-13T13:27:33', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '75e48d1f-a9de-488d-90e0-ef45502a54cc'	System	13 Dec 2020 18:27:37
User entered 'No (N)'	System	13 Dec 2020 18:27:37

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-12-13T13:27:36', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '75e48d1f-a9de-488d-90e0-ef45502a54cc'	System	13 Dec 2020 18:27:37
User entered '13 Dec 2020 13:27:36'	System	13 Dec 2020 18:27:37

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '11 Dec 2020 00:01'	System	19 Nov 2020 18:23:18

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '15 Dec 2020 23:59'	System	19 Nov 2020 18:23:18

FDA-CBER-2022-1614-3322629

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 18:23:18

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-12-18T16:59:06', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '91db50c9-8fe7-43a0-8d9e-a36bde7c1164'	System	18 Dec 2020 21:59:57
User entered 'Yes (Y)'	System	18 Dec 2020 21:59:57

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-12-18T16:59:14', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '91db50c9-8fe7-43a0-8d9e-a36bde7c1164'	System	18 Dec 2020 21:59:57
User entered 'No (N)'	System	18 Dec 2020 21:59:57

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-12-18T16:59:18', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '91db50c9-8fe7-43a0-8d9e-a36bde7c1164'	System	18 Dec 2020 21:59:57
User entered 'No (N)'	System	18 Dec 2020 21:59:57

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-12-18T16:59:26', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '91db50c9-8fe7-43a0-8d9e-a36bde7c1164'	System	18 Dec 2020 21:59:57
User entered 'Yes (Y)'	System	18 Dec 2020 21:59:57

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-12-18T16:59:37', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '91db50c9-8fe7-43a0-8d9e-a36bde7c1164'	System	18 Dec 2020 21:59:57
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	18 Dec 2020 21:59:57

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-12-18T16:59:49', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '91db50c9-8fe7-43a0-8d9e-a36bde7c1164'	System	18 Dec 2020 21:59:57
User entered '18 Dec 2020 16:59:49'	System	18 Dec 2020 21:59:57

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '18 Dec 2020 00:01'	System	19 Nov 2020 18:23:18

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '22 Dec 2020 23:59'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 18:23:18

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-12-25T00:01:32', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '419f213a-f38b-41db-941a-797d06f6c184'	System	25 Dec 2020 05:01:49
User entered 'No (N)'	System	25 Dec 2020 05:01:49

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-12-25T00:01:36', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '419f213a-f38b-41db-941a-797d06f6c184'	System	25 Dec 2020 05:01:49
User entered 'No (N)'	System	25 Dec 2020 05:01:49

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2020-12-25T00:01:40', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '419f213a-f38b-41db-941a-797d06f6c184'	System	25 Dec 2020 05:01:49
User entered '25 Dec 2020 00:01:40'	System	25 Dec 2020 05:01:49

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '25 Dec 2020 00:01'	System	19 Nov 2020 18:23:18

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '29 Dec 2020 23:59'	System	19 Nov 2020 18:23:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 18:23:18

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2021-01-01T00:12:20', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '991f3cbc-5544-4c31-b754-885affae8795'	System	01 Jan 2021 05:12:28
User entered 'No (N)'	System	01 Jan 2021 05:12:28

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2021-01-01T00:12:23', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '991f3cbc-5544-4c31-b754-885affae8795'	System	01 Jan 2021 05:12:28
User entered 'No (N)'	System	01 Jan 2021 05:12:28

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2021-01-01T00:12:26', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '991f3cbc-5544-4c31-b754-885affae8795'	System	01 Jan 2021 05:12:28
User entered '01 Jan 2021 00:12:26'	System	01 Jan 2021 05:12:28

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '01 Jan 2021 00:01'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '05 Jan 2021 23:59'	System	19 Nov 2020 18:23:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 18:23:18

FDA-CBER-2022-1614-3322651

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2021-01-09T08:40:25', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '14c3d6df-6361-4f7d-b28e-4daecac64ca0'	System	09 Jan 2021 13:40:34
User entered 'No (N)'	System	09 Jan 2021 13:40:34

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2021-01-09T08:40:28', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '14c3d6df-6361-4f7d-b28e-4daecac64ca0'	System	09 Jan 2021 13:40:34
User entered 'No (N)'	System	09 Jan 2021 13:40:34

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2021-01-09T08:40:31', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '14c3d6df-6361-4f7d-b28e-4daecac64ca0'	System	09 Jan 2021 13:40:34
User entered '09 Jan 2021 08:40:31'	System	09 Jan 2021 13:40:34

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '08 Jan 2021 00:01'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '12 Jan 2021 23:59'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 18:23:18

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2021-01-15T20:35:53', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'd527d604-c7e4-4965-a492-41227e4d35d9'	System	16 Jan 2021 01:36:02
User entered 'No (N)'	System	16 Jan 2021 01:36:02

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2021-01-15T20:35:56', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'd527d604-c7e4-4965-a492-41227e4d35d9'	System	16 Jan 2021 01:36:02
User entered 'No (N)'	System	16 Jan 2021 01:36:02

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2021-01-15T20:35:58', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'd527d604-c7e4-4965-a492-41227e4d35d9'	System	16 Jan 2021 01:36:02
User entered '15 Jan 2021 20:35:58'	System	16 Jan 2021 01:36:02

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '15 Jan 2021 00:01'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '19 Jan 2021 23:59'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2021-01-23T08:16:36', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '0b998c07-b049-4cd8-9ba1-9df70e1efe73'	System	23 Jan 2021 13:16:44
User entered 'No (N)'	System	23 Jan 2021 13:16:44

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2021-01-23T08:16:38', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '0b998c07-b049-4cd8-9ba1-9df70e1efe73'	System	23 Jan 2021 13:16:44
User entered 'No (N)'	System	23 Jan 2021 13:16:44

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2021-01-23T08:16:40', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '0b998c07-b049-4cd8-9ba1-9df70e1efe73'	System	23 Jan 2021 13:16:44
User entered '23 Jan 2021 08:16:40'	System	23 Jan 2021 13:16:44

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '22 Jan 2021 00:01'	System	19 Nov 2020 18:23:18

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '26 Jan 2021 23:59'	System	19 Nov 2020 18:23:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 18:23:18

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2021-01-31T09:46:11', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'dff0f0e4-162f-48cb-a5bc-cd1e30ac86a1'	System	31 Jan 2021 14:46:20
User entered 'No (N)'	System	31 Jan 2021 14:46:20

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2021-01-31T09:46:13', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'dff0f0e4-162f-48cb-a5bc-cd1e30ac86a1'	System	31 Jan 2021 14:46:20
User entered 'No (N)'	System	31 Jan 2021 14:46:20

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2021-01-31T09:46:15', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'dff0f0e4-162f-48cb-a5bc-cd1e30ac86a1'	System	31 Jan 2021 14:46:20
User entered '31 Jan 2021 09:46:15'	System	31 Jan 2021 14:46:20

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '29 Jan 2021 00:01'	System	19 Nov 2020 18:23:18

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '02 Feb 2021 23:59'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 18:23:18

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2021-02-05T00:01:27', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '1b5f14b3-88a1-41cd-812e-bc14bcd3316a'	System	05 Feb 2021 05:01:55
User entered 'No (N)'	System	05 Feb 2021 05:01:55

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2021-02-05T00:01:28', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '1b5f14b3-88a1-41cd-812e-bc14bcd3316a'	System	05 Feb 2021 05:01:55
User entered 'No (N)'	System	05 Feb 2021 05:01:55

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2021-02-05T00:01:31', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '1b5f14b3-88a1-41cd-812e-bc14bcd3316a'	System	05 Feb 2021 05:01:55
User entered '05 Feb 2021 00:01:31'	System	05 Feb 2021 05:01:55

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '05 Feb 2021 00:01'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '09 Feb 2021 23:59'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 18:23:18

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2021-02-12T00:01:12', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'a29e9e35-5bde-4a99-8ed2-960050b9a516'	System	12 Feb 2021 05:01:55
User entered 'No (N)'	System	12 Feb 2021 05:01:55

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2021-02-12T00:01:16', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'a29e9e35-5bde-4a99-8ed2-960050b9a516'	System	12 Feb 2021 05:01:55
User entered 'No (N)'	System	12 Feb 2021 05:01:55

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2021-02-12T00:01:19', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'a29e9e35-5bde-4a99-8ed2-960050b9a516'	System	12 Feb 2021 05:01:55
User entered '12 Feb 2021 00:01:19'	System	12 Feb 2021 05:01:55

FDA-CBER-2022-1614-3322684

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '12 Feb 2021 00:01'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '16 Feb 2021 23:59'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2021-02-19T14:39:53', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '9569829e-192c-4d2a-b980-a9dd4cbdb747'	System	19 Feb 2021 19:40:08
User entered 'No (N)'	System	19 Feb 2021 19:40:08

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2021-02-19T14:39:56', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '9569829e-192c-4d2a-b980-a9dd4cbdb747'	System	19 Feb 2021 19:40:08
User entered 'No (N)'	System	19 Feb 2021 19:40:08

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2021-02-19T14:40:00', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '9569829e-192c-4d2a-b980-a9dd4cbdb747'	System	19 Feb 2021 19:40:08
User entered '19 Feb 2021 14:40:00'	System	19 Feb 2021 19:40:08

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '19 Feb 2021 00:01'	System	19 Nov 2020 18:23:18

FDA-CBER-2022-1614-3322691

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '23 Feb 2021 23:59'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 18:23:18

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2021-02-26T07:00:23', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '17fadbcc-8e02-422b-87ae-2304dd3e4e33'	System	26 Feb 2021 12:00:33
User entered 'No (N)'	System	26 Feb 2021 12:00:33

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2021-02-26T07:00:27', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '17fadbcc-8e02-422b-87ae-2304dd3e4e33'	System	26 Feb 2021 12:00:33
User entered 'No (N)'	System	26 Feb 2021 12:00:33

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2021-02-26T07:00:30', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '17fadbcc-8e02-422b-87ae-2304dd3e4e33'	System	26 Feb 2021 12:00:33
User entered '26 Feb 2021 07:00:30'	System	26 Feb 2021 12:00:33

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '26 Feb 2021 00:01'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '02 Mar 2021 23:59'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 18:23:18

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2021-03-05T07:34:25-05:00', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '9ca3407d-5eab-4413-8e91-dc6a59387e6c'	System	05 Mar 2021 12:34:35
User entered 'No (N)'	System	05 Mar 2021 12:34:35

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2021-03-05T07:34:27-05:00', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '9ca3407d-5eab-4413-8e91-dc6a59387e6c'	System	05 Mar 2021 12:34:35
User entered 'No (N)'	System	05 Mar 2021 12:34:35

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2021-03-05T07:34:30-05:00', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '9ca3407d-5eab-4413-8e91-dc6a59387e6c'	System	05 Mar 2021 12:34:35
User entered '05 Mar 2021 07:34:30'	System	05 Mar 2021 12:34:35

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '05 Mar 2021 00:01'	System	19 Nov 2020 18:23:18

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '09 Mar 2021 23:59'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2021-03-12T10:48:59-05:00', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '76d5aa6d-235a-4468-b5e8-b3153dbe2a56'	System	12 Mar 2021 15:49:38
User entered 'No (N)'	System	12 Mar 2021 15:49:38

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2021-03-12T10:49:09-05:00', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '76d5aa6d-235a-4468-b5e8-b3153dbe2a56'	System	12 Mar 2021 15:49:38
User entered 'No (N)'	System	12 Mar 2021 15:49:38

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2021-03-12T10:49:33-05:00', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '76d5aa6d-235a-4468-b5e8-b3153dbe2a56'	System	12 Mar 2021 15:49:38
User entered '12 Mar 2021 10:49:33'	System	12 Mar 2021 15:49:38

FDA-CBER-2022-1614-3322708

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '12 Mar 2021 00:01'	System	19 Nov 2020 18:23:18

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '16 Mar 2021 23:59'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 18:23:18

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2021-03-19T13:51:44-04:00', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '39ffcfd3-e6c2-4d4e-9c4d-49992d4a5f06'	System	19 Mar 2021 17:51:51
User entered 'No (N)'	System	19 Mar 2021 17:51:51

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2021-03-19T13:51:46-04:00', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '39ffcfd3-e6c2-4d4e-9c4d-49992d4a5f06'	System	19 Mar 2021 17:51:51
User entered 'No (N)'	System	19 Mar 2021 17:51:51

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2021-03-19T13:51:49-04:00', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '39ffcfd3-e6c2-4d4e-9c4d-49992d4a5f06'	System	19 Mar 2021 17:51:51
User entered '19 Mar 2021 13:51:49'	System	19 Mar 2021 17:51:51

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '19 Mar 2021 00:01'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '23 Mar 2021 23:59'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 18:23:18

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2021-03-29T14:32:46-04:00', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '3408bdf5-fae2-4247-bfd4-da30bd2daaf3'	System	29 Mar 2021 18:32:55
User entered 'No (N)'	System	29 Mar 2021 18:32:55

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2021-03-29T14:32:48-04:00', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '3408bdf5-fae2-4247-bfd4-da30bd2daaf3'	System	29 Mar 2021 18:32:55
User entered 'No (N)'	System	29 Mar 2021 18:32:55

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2021-03-29T14:32:51-04:00', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '3408bdf5-fae2-4247-bfd4-da30bd2daaf3'	System	29 Mar 2021 18:32:55
User entered '29 Mar 2021 14:32:51'	System	29 Mar 2021 18:32:55

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '26 Mar 2021 00:01'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '30 Mar 2021 23:59'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 18:23:18

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2021-04-02T16:55:52-04:00', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '7d66145b-32e0-4086-b638-8107a73ed7ab'	System	02 Apr 2021 20:56:00
User entered 'No (N)'	System	02 Apr 2021 20:56:00

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2021-04-02T16:55:54-04:00', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '7d66145b-32e0-4086-b638-8107a73ed7ab'	System	02 Apr 2021 20:56:00
User entered 'No (N)'	System	02 Apr 2021 20:56:00

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2021-04-02T16:55:57-04:00', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '7d66145b-32e0-4086-b638-8107a73ed7ab'	System	02 Apr 2021 20:56:00
User entered '02 Apr 2021 16:55:57'	System	02 Apr 2021 20:56:00

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '02 Apr 2021 00:01'	System	19 Nov 2020 18:23:18

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '06 Apr 2021 23:59'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 18:23:18

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2021-04-09T06:42:48-04:00', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '8e9eda00-04e1-47cf-82b0-a3d927608b3c'	System	09 Apr 2021 10:42:56
User entered 'No (N)'	System	09 Apr 2021 10:42:56

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2021-04-09T06:42:50-04:00', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '8e9eda00-04e1-47cf-82b0-a3d927608b3c'	System	09 Apr 2021 10:42:56
User entered 'No (N)'	System	09 Apr 2021 10:42:56

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2021-04-09T06:42:53-04:00', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '8e9eda00-04e1-47cf-82b0-a3d927608b3c'	System	09 Apr 2021 10:42:56
User entered '09 Apr 2021 06:42:53'	System	09 Apr 2021 10:42:56

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '09 Apr 2021 00:01'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '13 Apr 2021 23:59'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 18:23:18

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2021-04-16T00:02:22-04:00', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '8890a956-0585-45f8-ab26-1159a4fb8b86'	System	16 Apr 2021 04:03:22
User entered 'No (N)'	System	16 Apr 2021 04:03:22

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2021-04-16T00:02:23-04:00', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '8890a956-0585-45f8-ab26-1159a4fb8b86'	System	16 Apr 2021 04:03:22
User entered 'No (N)'	System	16 Apr 2021 04:03:22

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2021-04-16T00:02:26-04:00', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '8890a956-0585-45f8-ab26-1159a4fb8b86'	System	16 Apr 2021 04:03:22
User entered '16 Apr 2021 00:02:26'	System	16 Apr 2021 04:03:22

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '16 Apr 2021 00:01'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '20 Apr 2021 23:59'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 18:23:18

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2021-04-23T16:46:34-04:00', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '7bf12b68-0aca-40ab-ab86-722a0ac579b0'	System	23 Apr 2021 20:46:46
User entered 'No (N)'	System	23 Apr 2021 20:46:46

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2021-04-23T16:46:35-04:00', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '7bf12b68-0aca-40ab-ab86-722a0ac579b0'	System	23 Apr 2021 20:46:46
User entered 'No (N)'	System	23 Apr 2021 20:46:46

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2021-04-23T16:46:38-04:00', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '7bf12b68-0aca-40ab-ab86-722a0ac579b0'	System	23 Apr 2021 20:46:46
User entered '23 Apr 2021 16:46:38'	System	23 Apr 2021 20:46:46

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '23 Apr 2021 00:01'	System	19 Nov 2020 18:23:18

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '27 Apr 2021 23:59'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 18:23:18

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2021-04-30T07:46:26-04:00', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '0868a113-22db-4ef4-b54d-07b1f9bb35c8'	System	30 Apr 2021 11:46:35
User entered 'No (N)'	System	30 Apr 2021 11:46:35

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2021-04-30T07:46:28-04:00', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '0868a113-22db-4ef4-b54d-07b1f9bb35c8'	System	30 Apr 2021 11:46:35
User entered 'No (N)'	System	30 Apr 2021 11:46:35

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2021-04-30T07:46:30-04:00', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: '0868a113-22db-4ef4-b54d-07b1f9bb35c8'	System	30 Apr 2021 11:46:35
User entered '30 Apr 2021 07:46:30'	System	30 Apr 2021 11:46:35

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '30 Apr 2021 00:01'	System	19 Nov 2020 18:23:18

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '04 May 2021 23:59'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 18:23:18

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '07 May 2021 00:01'	System	19 Nov 2020 18:23:18

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '11 May 2021 23:59'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 18:23:18

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '14 May 2021 00:01'	System	19 Nov 2020 18:23:18

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '18 May 2021 23:59'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '21 May 2021 00:01'	System	19 Nov 2020 18:23:18

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '25 May 2021 23:59'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '28 May 2021 00:01'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '01 Jun 2021 23:59'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 18:23:18

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '04 Jun 2021 00:01'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '08 Jun 2021 23:59'	System	19 Nov 2020 18:23:18

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '11 Jun 2021 00:01'	System	19 Nov 2020 18:23:18

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '15 Jun 2021 23:59'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 18:23:18

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '18 Jun 2021 00:01'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '22 Jun 2021 23:59'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '25 Jun 2021 00:01'	System	19 Nov 2020 18:23:18

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '29 Jun 2021 23:59'	System	19 Nov 2020 18:23:18

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 18:23:18

FDA-CBER-2022-1614-3322777

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '02 Jul 2021 00:01'	System	19 Nov 2020 18:23:18

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '06 Jul 2021 23:59'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 18:23:18

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '09 Jul 2021 00:01'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '13 Jul 2021 23:59'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '16 Jul 2021 00:01'	System	19 Nov 2020 18:23:18

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '20 Jul 2021 23:59'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 18:23:18

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '23 Jul 2021 00:01'	System	19 Nov 2020 18:23:18

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '27 Jul 2021 23:59'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '30 Jul 2021 00:01'	System	19 Nov 2020 18:23:18

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '03 Aug 2021 23:59'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '06 Aug 2021 00:01'	System	19 Nov 2020 18:23:18

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '10 Aug 2021 23:59'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '13 Aug 2021 00:01'	System	19 Nov 2020 18:23:18

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '17 Aug 2021 23:59'	System	19 Nov 2020 18:23:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 18:23:18

FDA-CBER-2022-1614-3322798

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '20 Aug 2021 00:01'	System	19 Nov 2020 18:23:18

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '24 Aug 2021 23:59'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '27 Aug 2021 00:01'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '31 Aug 2021 23:59'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 18:23:18

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '03 Sep 2021 00:01'	System	19 Nov 2020 18:23:18

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '07 Sep 2021 23:59'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '10 Sep 2021 00:01'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '14 Sep 2021 23:59'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 18:23:18

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '17 Sep 2021 00:01'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '21 Sep 2021 23:59'	System	19 Nov 2020 18:23:18

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '24 Sep 2021 00:01'	System	19 Nov 2020 18:23:18

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '28 Sep 2021 23:59'	System	19 Nov 2020 18:23:18

FDA-CBER-2022-1614-3322815

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '01 Oct 2021 00:01'	System	19 Nov 2020 18:23:18

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '05 Oct 2021 23:59'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '08 Oct 2021 00:01'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '12 Oct 2021 23:59'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 18:23:18

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '15 Oct 2021 00:01'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '19 Oct 2021 23:59'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 18:23:18

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '22 Oct 2021 00:01'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '26 Oct 2021 23:59'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '29 Oct 2021 00:01'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '02 Nov 2021 23:59'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 18:23:18

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '05 Nov 2021 00:01'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '09 Nov 2021 23:59'	System	19 Nov 2020 18:23:18

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '12 Nov 2021 00:01'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '16 Nov 2021 23:59'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '19 Nov 2021 00:01'	System	19 Nov 2020 18:23:18

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '23 Nov 2021 23:59'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 18:23:18

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '26 Nov 2021 00:01'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '30 Nov 2021 23:59'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 18:23:18

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '03 Dec 2021 00:01'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '07 Dec 2021 23:59'	System	19 Nov 2020 18:23:18

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '10 Dec 2021 00:01'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '14 Dec 2021 23:59'	System	19 Nov 2020 18:23:18

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '17 Dec 2021 00:01'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '21 Dec 2021 23:59'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 18:23:18

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '24 Dec 2021 00:01'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '28 Dec 2021 23:59'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '31 Dec 2021 00:01'	System	19 Nov 2020 18:23:18

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '04 Jan 2022 23:59'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '07 Jan 2022 00:01'	System	19 Nov 2020 18:23:18

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '11 Jan 2022 23:59'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 18:23:18

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '14 Jan 2022 00:01'	System	19 Nov 2020 18:23:18

FDA-CBER-2022-1614-3322862

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '18 Jan 2022 23:59'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '21 Jan 2022 00:01'	System	19 Nov 2020 18:23:18

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '25 Jan 2022 23:59'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 18:23:18

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '28 Jan 2022 00:01'	System	19 Nov 2020 18:23:18

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '01 Feb 2022 23:59'	System	19 Nov 2020 18:23:18

FDA-CBER-2022-1614-3322869

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 18:23:18

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '04 Feb 2022 00:01'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '08 Feb 2022 23:59'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '11 Feb 2022 00:01'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '15 Feb 2022 23:59'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 18:23:18

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '18 Feb 2022 00:01'	System	19 Nov 2020 18:23:18

FDA-CBER-2022-1614-3322877

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '22 Feb 2022 23:59'	System	19 Nov 2020 18:23:18

FDA-CBER-2022-1614-3322878

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '25 Feb 2022 00:01'	System	19 Nov 2020 18:23:18

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '01 Mar 2022 23:59'	System	19 Nov 2020 18:23:18

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 18:23:18

FDA-CBER-2022-1614-3322882

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '04 Mar 2022 00:01'	System	19 Nov 2020 18:23:18

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '08 Mar 2022 23:59'	System	19 Nov 2020 18:23:18

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '11 Mar 2022 00:01'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '15 Mar 2022 23:59'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '18 Mar 2022 00:01'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '22 Mar 2022 23:59'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '25 Mar 2022 00:01'	System	19 Nov 2020 18:23:18

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '29 Mar 2022 23:59'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '01 Apr 2022 00:01'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '05 Apr 2022 23:59'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 18:23:18

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '08 Apr 2022 00:01'	System	19 Nov 2020 18:23:18

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '12 Apr 2022 23:59'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '15 Apr 2022 00:01'	System	19 Nov 2020 18:23:18

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '19 Apr 2022 23:59'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '22 Apr 2022 00:01'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '26 Apr 2022 23:59'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 18:23:18

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '29 Apr 2022 00:01'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '03 May 2022 23:59'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '06 May 2022 00:01'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '10 May 2022 23:59'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '13 May 2022 00:01'	System	19 Nov 2020 18:23:18

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '17 May 2022 23:59'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '20 May 2022 00:01'	System	19 Nov 2020 18:23:18

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '24 May 2022 23:59'	System	19 Nov 2020 18:23:18

FDA-CBER-2022-1614-3322917

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '27 May 2022 00:01'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '31 May 2022 23:59'	System	19 Nov 2020 18:23:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '03 Jun 2022 00:01'	System	19 Nov 2020 18:23:18

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '07 Jun 2022 23:59'	System	19 Nov 2020 18:23:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 18:23:18

FDA-CBER-2022-1614-3322924

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '10 Jun 2022 00:01'	System	19 Nov 2020 18:23:18

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '14 Jun 2022 23:59'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '17 Jun 2022 00:01'	System	19 Nov 2020 18:23:18

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '21 Jun 2022 23:59'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '24 Jun 2022 00:01'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '28 Jun 2022 23:59'	System	19 Nov 2020 18:23:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '01 Jul 2022 00:01'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '05 Jul 2022 23:59'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '08 Jul 2022 00:01'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '12 Jul 2022 23:59'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '15 Jul 2022 00:01'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '19 Jul 2022 23:59'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 18:23:18

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '22 Jul 2022 00:01'	System	19 Nov 2020 18:23:18

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '26 Jul 2022 23:59'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '29 Jul 2022 00:01'	System	19 Nov 2020 18:23:18

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '02 Aug 2022 23:59'	System	19 Nov 2020 18:23:18

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '05 Aug 2022 00:01'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '09 Aug 2022 23:59'	System	19 Nov 2020 18:23:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 18:23:18

FDA-CBER-2022-1614-3322951

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '12 Aug 2022 00:01'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '16 Aug 2022 23:59'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '19 Aug 2022 00:01'	System	19 Nov 2020 18:23:18

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '23 Aug 2022 23:59'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '26 Aug 2022 00:01'	System	19 Nov 2020 18:23:18

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '30 Aug 2022 23:59'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 18:23:18

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '02 Sep 2022 00:01'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '06 Sep 2022 23:59'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '09 Sep 2022 00:01'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '13 Sep 2022 23:59'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '16 Sep 2022 00:01'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '20 Sep 2022 23:59'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '23 Sep 2022 00:01'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '27 Sep 2022 23:59'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '30 Sep 2022 00:01'	System	19 Nov 2020 18:23:18

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '04 Oct 2022 23:59'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '07 Oct 2022 00:01'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '11 Oct 2022 23:59'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '14 Oct 2022 00:01'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '18 Oct 2022 23:59'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 18:23:18

US3692001

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:06

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '21 Oct 2022 00:01'	System	19 Nov 2020 18:23:18

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '25 Oct 2022 23:59'	System	19 Nov 2020 18:23:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 18:23:18

FDA-CBER-2022-1614-3322984

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '28 Oct 2022 00:01'	System	19 Nov 2020 18:23:18

US3692001
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:06
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:23:18
Amendment Manager: User entered '01 Nov 2022 23:59'	System	19 Nov 2020 18:23:18

US3692001

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:24:06

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:05:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2021-03-05T07:34:40-05:00', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'c38d001b-3559-49bc-abc3-bb88e921d5f2'	System	05 Mar 2021 12:34:49
User entered 'No (N)'	System	05 Mar 2021 12:34:49

US3692001

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:24:06

Date & Time of Submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:05:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8842D19D-F660-4A88-B74E-1353DAE2BDDA)', Time: '2021-03-05T07:34:46-05:00', User OID: 'PatientReportedOutcome (US3692001)', ODM File OID: 'c38d001b-3559-49bc-abc3-bb88e921d5f2'	System	05 Mar 2021 12:34:49
User entered '05 Mar 2021 07:34:46'	System	05 Mar 2021 12:34:49

US3692001
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:24:06

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'Yes (Y)'	Patti Vasquez (b) (4) (b) (4)	17 Nov 2020 16:13:41

Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:24:06
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '17 Nov 2020'	Patti Vasquez (b) (4) (b) (4)	17 Nov 2020 16:13:41

US3692001
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:24:06
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'Contact Made (CONTACT MADE)'	Patti Vasquez (b) (4) (b) (4)	17 Nov 2020 16:13:41

US3692001
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:24:06
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered empty.	Patti Vasquez (b) (4) (b) (4)	17 Nov 2020 16:13:41

US3692001
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:24:06

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'Yes (Y)'	Patti Vasquez (b) (4) (b) (4)	17 Nov 2020 16:13:48

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:44:07
User entered '1'	System	17 Nov 2020 16:13:48

US3692001
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:24:06

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:20:37
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'Yes (Y)'	Joy Wannamaker (b) (4) (b) (4)	22 Dec 2020 14:44:25

US3692001

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:24:06

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:20:37
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '22 Dec 2020'	Joy Wannamaker (b) (4) (b) (4)	22 Dec 2020 14:44:25

US3692001
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:24:06
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:20:37
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'Contact Made (CONTACT MADE)'	Joy Wannamaker (b) (4) (b) (4)	22 Dec 2020 14:44:25

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:20:37
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'Pt hospitalized for gastric ulcers from 14 Dec - 16 Dec. Chart and communications added to pt chart. New meds and procedure added. New consent reviewed and signed.'	Joy Wannamaker (b) (4) (b) (4)	22 Dec 2020 14:44:25

FDA-CBER-2022-1614-3322998

US3692001
Folder: Safety Call Day 119 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:24:06

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:20:37
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'Yes (Y)'	Joy Wannamaker (b) (4) (b) (4)	22 Dec 2020 14:44:36

FDA-CBER-2022-1614-3322999

US3692001
Folder: Safety Call Day 119 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:24:06
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:20:37
User entered '1'	System	22 Dec 2020 14:44:36

US3692001
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:24:06

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:20:37
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'Yes (Y)'	Oesa Vinesett (b) (4) (b) (4)	19 Jan 2021 17:38:37

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:20:37
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '18 Jan 2021'	Oesa Vinesett (b) (4) (b) (4)	19 Jan 2021 17:38:37

FDA-CBER-2022-1614-3323002

US3692001
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:24:06
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:20:37
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'Contact Made (CONTACT MADE)'	Oesa Vinesett (b) (4) (b) (4)	19 Jan 2021 17:38:37

US3692001
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:24:06
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:20:37
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered empty.	Oesa Vinesett (b) (4) (b) (4)	19 Jan 2021 17:38:37

US3692001
Folder: Safety Call Day 149 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:24:06

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:20:37
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'Yes (Y)'	Maria Stetson (b) (4) (b) (4)	12 Feb 2021 16:45:44

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:20:37
User entered '1'	System	12 Feb 2021 16:45:44

US3692001
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:24:06

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:20:37
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'Yes (Y)'	Camille O'Reilly (b) (4) (b) (4)	18 Feb 2021 21:04:27

US3692001
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:24:06

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:20:37
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '18 Feb 2021'	Camille O'Reilly (b) (4) (b) (4)	18 Feb 2021 21:04:27

US3692001
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:24:06

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:20:37
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'Contact Made (CONTACT MADE)'	Camille O'Reilly (b) (4) (b) (4)	18 Feb 2021 21:04:27

US3692001
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:24:06
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:20:37
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered empty.	Camille O'Reilly (b) (4) (b) (4)	18 Feb 2021 21:04:27

US3692001
Folder: Safety Call Day 179 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:24:06

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:20:37
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'Yes (Y)'	Camille O'Reilly (b) (4) (b) (4)	18 Feb 2021 21:04:34

US3692001
Folder: Safety Call Day 179 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:24:06
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:20:37
User entered '1'	System	18 Feb 2021 21:04:34

US3692001

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:24:06

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:20:37
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Mar 2021 19:59:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Mar 2021 15:22:50

US3692001

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:24:06

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:20:37
User signature succeeded.	Cynthia Gay (b) (4)	19 Mar 2021 19:59:42
	(b) (4)	
User entered '19 Mar 2021'	(b) (4), (b) (6)	19 Mar 2021 15:22:50

US3692001
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:24:06

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:20:37
User signature succeeded.	Cynthia Gay (b) (4)	19 Mar 2021 19:59:42
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	19 Mar 2021 15:22:50

US3692001
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:24:06
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:20:37
User entered 'VISIT4'	System	19 Mar 2021 15:22:50

US3692001
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:06
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:20:37
User signature succeeded.	Cynthia Gay (b) (4)	01 Apr 2021 21:15:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:21:34

US3692001
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:06
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:20:37
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	01 Apr 2021 21:15:33
User entered '19 Mar 2021'	(b) (4), (b) (6)	30 Mar 2021 21:21:34

US3692001
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:06
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:20:37
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	01 Apr 2021 21:15:33
User entered '09:32'	(b) (4), (b) (6)	30 Mar 2021 21:21:34

US3692001
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:06
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:20:37
User entered '19 Mar 2021 09:32'	System	30 Mar 2021 21:21:34

Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:06
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:20:37
User signature succeeded.	Cynthia Gay (b) (4)	01 Apr 2021 21:15:33
User entered '36.9' C	(b) (4), (b) (6)	30 Mar 2021 21:21:34

US3692001
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:06

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:20:37
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	01 Apr 2021 21:15:33
User entered 'Oral (Oral)'	(b) (4), (b) (6)	30 Mar 2021 21:21:34

US3692001
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:06
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:20:37
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	01 Apr 2021 21:15:33
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 21:21:34

US3692001
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:06

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:20:37
User signature succeeded.	Cynthia Gay (b) (4)	01 Apr 2021 21:15:33
User entered '73'	(b) (4), (b) (6)	30 Mar 2021 21:21:34

US3692001
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:06
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:20:37
User entered 'bpm'	System	30 Mar 2021 21:21:34

US3692001
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:06
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:20:37
User signature succeeded.	Cynthia Gay (b) (4)	01 Apr 2021 21:15:33
User entered '16'	(b) (4), (b) (6)	30 Mar 2021 21:21:34

US3692001
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:06
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:20:37
User entered 'breaths/min'	System	30 Mar 2021 21:21:34

FDA-CBER-2022-1614-3323027

US3692001
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:06
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:20:37
User signature succeeded.	Cynthia Gay (b) (4)	01 Apr 2021 21:15:33
User entered '124'	(b) (4), (b) (6)	30 Mar 2021 21:21:34

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:20:37
User entered 'mmHg'	System	30 Mar 2021 21:21:34

FDA-CBER-2022-1614-3323029

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:20:37
User signature succeeded.	Cynthia Gay (b) (4)	01 Apr 2021 21:15:33
User entered '81'	(b) (4), (b) (6)	30 Mar 2021 21:21:34

FDA-CBER-2022-1614-3323030

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:20:37
User entered 'mmHg'	System	30 Mar 2021 21:21:34

FDA-CBER-2022-1614-3323031

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:20:37

US3692001
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:06
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:20:37

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:20:37
User signature succeeded.	Cynthia Gay (b) (4)	19 Mar 2021 19:59:42
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	19 Mar 2021 15:23:14

US3692001
Folder: Visit 4 Day 209 (1)
Form: Physical Examination
Generated On: 10 Jun 2021 09:24:06
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:20:37
User signature succeeded.	Cynthia Gay (b) (4)	19 Mar 2021 19:59:42
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 15:23:14

Folder: Visit 4 Day 209 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:24:06

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:20:37
User signature succeeded.	Cynthia Gay (b) (4)	19 Mar 2021 19:59:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Mar 2021 15:23:33

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:20:37
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Mar 2021 19:59:42
User entered '19 Mar 2021'	(b) (4), (b) (6)	19 Mar 2021 15:23:33

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:20:37
User signature succeeded.	Cynthia Gay (b) (4)	19 Mar 2021 19:59:42
User entered '09:44'	(b) (4), (b) (6)	19 Mar 2021 15:23:33

FDA-CBER-2022-1614-3323038

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:20:37
User entered '19 Mar 2021 09:44'	System	19 Mar 2021 15:23:33

FDA-CBER-2022-1614-3323039

US3692001
Folder: Visit 4 Day 209 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:24:06

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:20:37
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Mar 2021 19:59:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Mar 2021 15:23:37

US3692001
Folder: Visit 4 Day 209 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:24:06
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 11:20:37
User entered '1'	System	19 Mar 2021 15:23:37

US3692001
Folder: Safety Call Day 239 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:24:06

Was Contact Attempted?

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	22 Apr 2021 18:26:17
User entered 'Yes (Y)'	Camille O'Reilly (b) (4) (b) (4)	19 Apr 2021 14:40:41

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	22 Apr 2021 18:26:17
User entered '19 Apr 2021'	Camille O'Reilly (b) (4) (b) (4)	19 Apr 2021 14:40:41

FDA-CBER-2022-1614-3323043

Please select one status for the follow-up contact

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	22 Apr 2021 18:26:17
User entered 'Contact Made (CONTACT MADE)'	Camille O'Reilly (b) (4) (b) (4)	19 Apr 2021 14:40:41

FDA-CBER-2022-1614-3323044

US3692001
Folder: Safety Call Day 239 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:24:06
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	22 Apr 2021 18:26:17
User entered empty.	Camille O'Reilly (b) (4) (b) (4)	19 Apr 2021 14:40:41

US3692001

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:24:06

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	22 Apr 2021 18:26:17
User entered 'Yes (Y)'	Camille O'Reilly (b) (4) (b) (4)	19 Apr 2021 14:40:48

US3692001
Folder: Safety Call Day 239 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:24:06
Continuing Flag

Audit	User	Time (GMT)
User entered '1'	System	19 Apr 2021 14:40:48

US3692001

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:24:06

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'Yes (Y)'	Erin Cardot (b) (4) (b) (4)	09 Jan 2021 16:07:46

FDA-CBER-2022-1614-3323048

US3692001

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:24:06

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '9 Jan 2021'	Erin Cardot (b) (4) (b) (4)	09 Jan 2021 16:07:46

Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:24:06

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'Clinic (Clinic)'	Erin Cardot (b) (4) (b) (4)	09 Jan 2021 16:07:46

US3692001
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:24:06
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User entered 'UNBLND_DECIDE'	System	09 Jan 2021 16:07:46

US3692001

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:24:06

Date of updated informed consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '9 Jan 2021'	Erin Cardot (b) (4) (b) (4)	09 Jan 2021 16:08:04

US3692001

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:24:06

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	12 Mar 2021 19:16:58
User entered '0'	Erin Cardot (b) (4) (b) (4)	08 Mar 2021 15:40:38
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 17:40:29

US3692001
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 09:24:06
Was the participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'Yes (Y)'	Erin Cardot (b) (4) (b) (4)	09 Jan 2021 16:08:04

US3692001

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:24:06

Under what version of the Protocol was the Participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	12 Mar 2021 19:16:58
User entered 'Amendment 6 or later (Amendment 6 or later)'	Erin Cardot (b) (4) (b) (4)	08 Mar 2021 15:40:38
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 17:40:29

US3692001

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:24:06

Date of unblinding *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '9 Jan 2021'	Erin Cardot (b) (4) (b) (4)	09 Jan 2021 16:08:04

US3692001

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:24:06

Participant randomization assignment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'Placebo (Placebo)'	Erin Cardot (b) (4) (b) (4)	09 Jan 2021 16:08:04

US3692001

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:24:06

Actual Dose 1

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 13:01:14
User entered 'Placebo (Placebo)'	Erin Cardot (b) (4) (b) (4)	09 Jan 2021 16:08:04

US3692001

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:24:06

Actual Dose 2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 13:01:14
User entered 'Placebo (Placebo)'	Erin Cardot (b) (4) (b) (4)	09 Jan 2021 16:08:04

US3692001

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:24:06

Will participant receive mRNA-1273?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'Yes (Y)'	Erin Cardot (b) (4) (b) (4)	09 Jan 2021 16:08:04

US3692001

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:24:06

Placebo Only Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User entered '1'	System	09 Jan 2021 16:08:04

US3692001
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 09:24:06
Continuing with mRNA-1273

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User entered '1'	System	09 Jan 2021 16:08:04

US3692001

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:24:06

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	05 Mar 2021 20:57:21
User entered missing code ND - Not Done.	Mandy Tipton (b) (4) (b) (4)	11 Jan 2021 21:35:40

US3692001

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:24:06

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	05 Mar 2021 20:57:21
User entered missing code ND - Not Done.	Mandy Tipton (b) (4) (b) (4)	11 Jan 2021 21:35:40

US3692001
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 09:24:06

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User entered empty.	System	11 Jan 2021 21:35:40
DataPoint set to visible.	System	09 Jan 2021 16:08:04

US3692001
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 09:24:06

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	05 Mar 2021 20:57:21
User entered missing code ND - Not Done.	Mandy Tipton (b) (4) (b) (4)	11 Jan 2021 21:35:40

US3692001
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 09:24:06
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	05 Mar 2021 20:57:21
User entered missing code ND - Not Done.	Mandy Tipton (b) (4) (b) (4)	11 Jan 2021 21:35:40

US3692001
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 09:24:06

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User entered empty.	System	11 Jan 2021 21:35:40
DataPoint set to visible.	System	09 Jan 2021 16:08:04

US3692001

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:06

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User accepted default value 'Pre-Dose (PREDOSE)'	Mandy Tipton (b) (4) (b) (4)	11 Jan 2021 21:35:40

US3692001

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:06

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	05 Mar 2021 20:57:21
User entered 'Yes (Y)'	Mandy Tipton (b) (4) (b) (4)	11 Jan 2021 21:35:40

US3692001

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:06

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	05 Mar 2021 20:57:21
Query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	04 Mar 2021 14:16:44
Comment added 'Data is correct. Day 0 and OL-1 split into 2 visits.'.	Mandy Tipton (b) (4) (b) (4)	26 Jan 2021 01:05:00
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	11 Jan 2021 21:35:40
User entered '11 Jan 2021'	Mandy Tipton (b) (4) (b) (4)	11 Jan 2021 21:35:40

US3692001

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:06

Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	05 Mar 2021 20:57:21
User entered '10:53'	Mandy Tipton (b) (4) (b) (4)	11 Jan 2021 21:35:40

US3692001

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:06

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User entered '11 Jan 2021 10:53'	System	11 Jan 2021 21:35:40

US3692001

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:06

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	05 Mar 2021 20:57:21
User entered '36.3' C	Mandy Tipton (b) (4) (b) (4)	11 Jan 2021 21:35:40

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:06

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	05 Mar 2021 20:57:21
User entered 'Oral (Oral)'	Mandy Tipton (b) (4) (b) (4)	11 Jan 2021 21:35:40

US3692001

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:06

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	05 Mar 2021 20:57:21
User entered empty.	Mandy Tipton (b) (4) (b) (4)	11 Jan 2021 21:35:40

US3692001

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:06

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	05 Mar 2021 20:57:21
User entered '73'	Mandy Tipton (b) (4) (b) (4)	11 Jan 2021 21:35:40

US3692001
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:24:06
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User entered 'bpm'	System	11 Jan 2021 21:35:40

US3692001

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:06

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	05 Mar 2021 20:57:21
User entered '16'	Mandy Tipton (b) (4) (b) (4)	11 Jan 2021 21:35:40

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User entered 'breaths/min'	System	11 Jan 2021 21:35:40

US3692001

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:06

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	05 Mar 2021 20:57:21
User entered '123'	Mandy Tipton (b) (4) (b) (4)	11 Jan 2021 21:35:40

US3692001

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:06

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User entered 'mmHg'	System	11 Jan 2021 21:35:40

US3692001

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:06

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	05 Mar 2021 20:57:21
User entered '75'	Mandy Tipton (b) (4) (b) (4)	11 Jan 2021 21:35:40

US3692001

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:06

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User entered 'mmHg'	System	11 Jan 2021 21:35:40

US3692001

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:24:06

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	05 Mar 2021 20:57:21
User entered missing code ND - Not Done.	Mandy Tipton (b) (4) (b) (4)	11 Jan 2021 21:35:40

US3692001
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 09:24:06
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	05 Mar 2021 20:57:21
User entered missing code ND - Not Done.	Mandy Tipton (b) (4) (b) (4)	11 Jan 2021 21:35:40

US3692001
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 09:24:06

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User entered empty.	System	11 Jan 2021 21:35:40
DataPoint set to visible.	System	09 Jan 2021 16:08:04

US3692001

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:06

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User accepted default value 'Post-Dose (POSTDOSE)'	Mandy Tipton (b) (4) (b) (4)	11 Jan 2021 21:35:40

US3692001

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:06

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	05 Mar 2021 20:57:21
User entered 'Yes (Y)'	Mandy Tipton (b) (4) (b) (4)	11 Jan 2021 21:35:40

US3692001

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:06

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	05 Mar 2021 20:57:21
Query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	04 Mar 2021 14:16:49
Comment added 'Date is correct. Day 0 and OL-1 visits conducted over 2 dates.'.	Mandy Tipton (b) (4) (b) (4)	28 Jan 2021 12:45:33
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	11 Jan 2021 21:35:40
User entered '11 Jan 2021'	Mandy Tipton (b) (4) (b) (4)	11 Jan 2021 21:35:40

US3692001

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:06

Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	05 Mar 2021 20:57:21
User entered '12:33'	Mandy Tipton (b) (4) (b) (4)	11 Jan 2021 21:35:40

US3692001

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:06

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User entered '11 Jan 2021 12:33'	System	11 Jan 2021 21:35:40

US3692001

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:06

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	05 Mar 2021 20:57:21
User entered '36.8' C	Mandy Tipton (b) (4) (b) (4)	11 Jan 2021 21:35:40

Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:24:06

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	05 Mar 2021 20:57:21
User entered 'Oral (Oral)'	Mandy Tipton (b) (4) (b) (4)	11 Jan 2021 21:35:40

FDA-CBER-2022-1614-3323094

US3692001

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:06

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	05 Mar 2021 20:57:21
User entered empty.	Mandy Tipton (b) (4) (b) (4)	11 Jan 2021 21:35:40

US3692001

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:06

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	05 Mar 2021 20:57:21
User entered '60'	Mandy Tipton (b) (4) (b) (4)	11 Jan 2021 21:35:40

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User entered 'bpm'	System	11 Jan 2021 21:35:40

US3692001

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:06

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	05 Mar 2021 20:57:21
User entered '16'	Mandy Tipton (b) (4) (b) (4)	11 Jan 2021 21:35:40

US3692001

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:06

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User entered 'breaths/min'	System	11 Jan 2021 21:35:40

US3692001

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:06

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	05 Mar 2021 20:57:21
User entered '111'	Mandy Tipton (b) (4) (b) (4)	11 Jan 2021 21:35:40

US3692001

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:06

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User entered 'mmHg'	System	11 Jan 2021 21:35:40

US3692001

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:06

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	05 Mar 2021 20:57:21
User entered '76'	Mandy Tipton (b) (4) (b) (4)	11 Jan 2021 21:35:40

US3692001

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:06

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User entered 'mmHg'	System	11 Jan 2021 21:35:40

Folder: Participant Decision Visit / OL-D1 (1)
Form: Physical Examination
Generated On: 10 Jun 2021 09:24:06

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'Yes (Y)'	Erin Cardot (b) (4) (b) (4)	09 Jan 2021 16:08:15

FDA-CBER-2022-1614-3323104

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '9 Jan 2021'	Erin Cardot (b) (4) (b) (4)	09 Jan 2021 16:08:15

US3692001

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:24:06

Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'Yes (Y)'	Mandy Tipton (b) (4) (b) (4)	11 Jan 2021 18:03:32

US3692001

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:24:06

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered empty.	Mandy Tipton (b) (4) (b) (4)	11 Jan 2021 18:03:32

US3692001

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:24:06

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered empty.	Mandy Tipton (b) (4) (b) (4)	11 Jan 2021 18:03:32

US3692001

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:24:06

What was the study treatment? (Unblinded)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User entered 'mRNA-1273'	System	11 Jan 2021 18:03:32
DataPoint set to visible.	System	09 Jan 2021 16:08:04

US3692001

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:24:06

What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:32:10
User closed query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	12 Jan 2021 10:22:15
Query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' answered with 'Date is correct. Day 0 and OL-1 visits were conducted on separate days.' (Site from System).	Mandy Tipton (b) (4) (b) (4)	11 Jan 2021 18:05:55
User opened query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	System	11 Jan 2021 18:03:32
User entered '11 Jan 2021'	Mandy Tipton (b) (4) (b) (4)	11 Jan 2021 18:03:32

Folder: Participant Decision Visit / OL-D1 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:24:06

What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '12:03'	Mandy Tipton (b) (4) (b) (4)	11 Jan 2021 18:03:32

Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User entered '11 Jan 2021 12:03'	System	11 Jan 2021 18:03:32

US3692001

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:24:06

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'Left Arm (LEFT ARM)'	Mandy Tipton (b) (4) (b) (4)	11 Jan 2021 18:03:32

FDA-CBER-2022-1614-3323113

US3692001

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:24:06

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User entered 'ONCE'	System	11 Jan 2021 18:03:32

US3692001

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:24:06

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User entered 'INTRAMUSCULAR'	System	11 Jan 2021 18:03:32

US3692001

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:24:06

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'Yes (Y)'	Erin Cardot (b) (4) (b) (4)	09 Jan 2021 16:08:31

Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:24:06

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '9 Jan 2021'	Erin Cardot (b) (4) (b) (4)	09 Jan 2021 16:08:31

FDA-CBER-2022-1614-3323117

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '10:30'	Erin Cardot (b) (4) (b) (4)	09 Jan 2021 16:08:31

FDA-CBER-2022-1614-3323118

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User entered '9 Jan 2021 10:30'	System	09 Jan 2021 16:08:31

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:24:06

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'Yes (Y)'	Erin Cardot (b) (4) (b) (4)	09 Jan 2021 16:08:46

Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 10 Jun 2021 09:24:06

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '9 Jan 2021'	Erin Cardot (b) (4) (b) (4)	09 Jan 2021 16:08:46

US3692001

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:24:06

Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '10:35'	Erin Cardot (b) (4) (b) (4)	09 Jan 2021 16:08:46

US3692001

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:24:06

Collection Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User entered '9 Jan 2021 10:35'	System	09 Jan 2021 16:08:46

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'Yes (Y)'	Erin Cardot (b) (4) (b) (4)	09 Jan 2021 16:08:50

US3692001
Folder: Participant Decision Visit / OL-D1 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:24:06
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User entered '1'	System	09 Jan 2021 16:08:50

US3692001
Folder: Safety Call OL-D8 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:24:06

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:18:38
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'Yes (Y)'	Camille O'Reilly (b) (4) (b) (4)	18 Jan 2021 17:42:20

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:18:38
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '18 Jan 2021'	Camille O'Reilly (b) (4) (b) (4)	18 Jan 2021 17:42:20

FDA-CBER-2022-1614-3323127

US3692001
Folder: Safety Call OL-D8 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:24:06

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:18:38
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'Contact Made (CONTACT MADE)'	Camille O'Reilly (b) (4) (b) (4)	18 Jan 2021 17:42:20

US3692001
Folder: Safety Call OL-D8 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:24:06
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:18:38
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered empty.	Camille O'Reilly (b) (4) (b) (4)	18 Jan 2021 17:42:20

US3692001

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:24:06

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:18:38
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'Yes (Y)'	Camille O'Reilly (b) (4) (b) (4)	18 Jan 2021 17:42:28

US3692001

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:24:06

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:18:38
User entered '1'	System	18 Jan 2021 17:42:28

US3692001

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:24:06

OLD29 Placebo Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:18:38
User entered '1'	System	18 Jan 2021 17:42:28
DataPoint set to visible.	System	18 Jan 2021 17:42:28

US3692001
Folder: OL-D29 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:24:06

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'Yes (Y)'	Maria Stetson (b) (4) (b) (4)	08 Feb 2021 18:35:49

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '08 Feb 2021'	Maria Stetson (b) (4) (b) (4)	08 Feb 2021 18:35:49

US3692001

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:24:06

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'Clinic (Clinic)'	Maria Stetson (b) (4) (b) (4)	08 Feb 2021 18:35:49

US3692001
Folder: OL-D29 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:24:06
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User entered 'OLD29'	System	08 Feb 2021 18:35:49

US3692001
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:24:06
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User accepted default value 'Pre-Dose (PREDOSE)'	Maria Stetson (b) (4) (b) (4)	08 Feb 2021 18:38:10

US3692001

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:06

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'Yes (Y)'	Maria Stetson (b) (4) (b) (4)	08 Feb 2021 18:38:10

US3692001

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:06

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '08 Feb 2021'	Maria Stetson (b) (4) (b) (4)	08 Feb 2021 18:38:10

US3692001

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:06

Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '12:29'	Maria Stetson (b) (4) (b) (4)	08 Feb 2021 18:38:10

US3692001

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:06

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User entered '08 Feb 2021 12:29'	System	08 Feb 2021 18:38:10

US3692001

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:06

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '36.9' C	Maria Stetson (b) (4) (b) (4)	08 Feb 2021 18:38:10

US3692001

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:06

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'Oral (Oral)'	Maria Stetson (b) (4) (b) (4)	08 Feb 2021 18:38:10

US3692001
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:24:06
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered empty.	Maria Stetson (b) (4) (b) (4)	08 Feb 2021 18:38:10

US3692001

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:06

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '61'	Maria Stetson (b) (4) (b) (4)	08 Feb 2021 18:38:10

US3692001
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:24:06
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User entered 'bpm'	System	08 Feb 2021 18:38:10

US3692001

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:06

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '18'	Maria Stetson (b) (4) (b) (4)	08 Feb 2021 18:38:10

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User entered 'breaths/min'	System	08 Feb 2021 18:38:10

FDA-CBER-2022-1614-3323148

US3692001

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:06

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '133'	Maria Stetson (b) (4) (b) (4)	08 Feb 2021 18:38:10

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User entered 'mmHg'	System	08 Feb 2021 18:38:10

FDA-CBER-2022-1614-3323150

US3692001

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:24:06

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '65'	Maria Stetson (b) (4) (b) (4)	08 Feb 2021 18:38:10

US3692001
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:24:06
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User entered 'mmHg'	System	08 Feb 2021 18:38:10

US3692001
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:24:06
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User accepted default value 'Post-Dose (POSTDOSE)'	Maria Stetson (b) (4) (b) (4)	08 Feb 2021 18:38:10

US3692001

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:06

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'Yes (Y)'	Maria Stetson (b) (4) (b) (4)	08 Feb 2021 18:38:10

US3692001

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:06

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '08 Feb 2021'	Maria Stetson (b) (4) (b) (4)	08 Feb 2021 18:38:10

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '13:24'	Maria Stetson (b) (4) (b) (4)	08 Feb 2021 18:38:10

FDA-CBER-2022-1614-3323156

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User entered '08 Feb 2021 13:24'	System	08 Feb 2021 18:38:10

FDA-CBER-2022-1614-3323157

US3692001
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:24:06
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '36.8' C	Maria Stetson (b) (4) (b) (4)	08 Feb 2021 18:38:10

US3692001

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:06

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'Oral (Oral)'	Maria Stetson (b) (4) (b) (4)	08 Feb 2021 18:38:10

US3692001
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:24:06
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered empty.	Maria Stetson (b) (4) (b) (4)	08 Feb 2021 18:38:10

US3692001

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:06

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '58'	Maria Stetson (b) (4) (b) (4)	08 Feb 2021 18:38:10

US3692001
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:24:06
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User entered 'bpm'	System	08 Feb 2021 18:38:10

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '18'	Maria Stetson (b) (4) (b) (4)	08 Feb 2021 18:38:10

FDA-CBER-2022-1614-3323163

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User entered 'breaths/min'	System	08 Feb 2021 18:38:10

US3692001

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:24:06

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '121'	Maria Stetson (b) (4) (b) (4)	08 Feb 2021 18:38:10

US3692001
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:24:06
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User entered 'mmHg'	System	08 Feb 2021 18:38:10

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '74'	Maria Stetson (b) (4) (b) (4)	08 Feb 2021 18:38:10

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User entered 'mmHg'	System	08 Feb 2021 18:38:10

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'Yes (Y)'	Maria Stetson (b) (4) (b) (4)	08 Feb 2021 18:39:52

FDA-CBER-2022-1614-3323169

US3692001

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:24:06

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '08 Feb 2021'	Maria Stetson (b) (4) (b) (4)	08 Feb 2021 18:39:52

US3692001
Folder: OL-D29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:24:06

Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'Yes (Y)'	Maria Stetson (b) (4) (b) (4)	08 Feb 2021 18:41:40

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered empty.	Maria Stetson (b) (4) (b) (4)	08 Feb 2021 18:41:40

FDA-CBER-2022-1614-3323172

US3692001

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:24:06

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered empty.	Maria Stetson (b) (4) (b) (4)	08 Feb 2021 18:41:40

US3692001

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:24:06

What was the study treatment? (Unblinded)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User entered 'mRNA-1273'	System	08 Feb 2021 18:41:40
DataPoint set to visible.	System	18 Jan 2021 17:42:28

What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '08 Feb 2021'	Maria Stetson (b) (4) (b) (4)	08 Feb 2021 18:41:40

FDA-CBER-2022-1614-3323175

US3692001

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:24:06

What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '12:54'	Maria Stetson (b) (4) (b) (4)	08 Feb 2021 18:41:40

Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User entered '08 Feb 2021 12:54'	System	08 Feb 2021 18:41:40

FDA-CBER-2022-1614-3323177

US3692001
Folder: OL-D29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:24:06

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'Left Arm (LEFT ARM)'	Maria Stetson (b) (4) (b) (4)	08 Feb 2021 18:41:40

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User entered 'ONCE'	System	08 Feb 2021 18:41:40

FDA-CBER-2022-1614-3323179

US3692001
Folder: OL-D29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:24:06

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User entered 'INTRAMUSCULAR'	System	08 Feb 2021 18:41:40

US3692001
Folder: OL-D29 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:24:06

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'Yes (Y)'	Maria Stetson (b) (4) (b) (4)	08 Feb 2021 18:43:04

US3692001

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:24:06

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:51:46
User entered '1'	System	08 Feb 2021 18:43:04

US3692001
Folder: Safety Call OL-D36 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:24:06

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:15:04
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'Yes (Y)'	Patti Vasquez (b) (4) (b) (4)	15 Feb 2021 13:41:27

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:15:04
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '15 Feb 2021'	Patti Vasquez (b) (4) (b) (4)	15 Feb 2021 13:41:27

US3692001
Folder: Safety Call OL-D36 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:24:06
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:15:04
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'Contact Made (CONTACT MADE)'	Patti Vasquez (b) (4) (b) (4)	15 Feb 2021 13:41:27

US3692001
Folder: Safety Call OL-D36 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:24:06
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:15:04
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered empty.	Patti Vasquez (b) (4) (b) (4)	15 Feb 2021 13:41:27

US3692001
Folder: Safety Call OL-D36 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:24:06
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:15:04
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'Yes (Y)'	Patti Vasquez (b) (4) (b) (4)	15 Feb 2021 13:41:33

US3692001
Folder: Safety Call OL-D36 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:24:06
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:15:04
User entered '1'	System	15 Feb 2021 13:41:33

US3692001
Folder: OL-D57 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:24:06
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:53
User signature succeeded.	Cynthia Gay (b) (4)	19 Mar 2021 19:59:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Mar 2021 15:20:34

US3692001
Folder: OL-D57 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:24:06

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:53
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Mar 2021 19:59:42
User entered '19 Mar 2021'	(b) (4), (b) (6)	19 Mar 2021 15:20:34

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:53
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Mar 2021 19:59:42
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	19 Mar 2021 15:20:34

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:53
User entered 'OLD57'	System	19 Mar 2021 15:20:34

US3692001
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:06

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:53
User closed query 'Visit 4 Day 209 and Visit OL-D57 are both dated 19Mar2021. However, the data on the Vital Signs in these two visits do not match. If confirmed the visits occurred on the same day, the data must match. Please review and reconcile. Thank you' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 20:13:55
Query 'Visit 4 Day 209 and Visit OL-D57 are both dated 19Mar2021. However, the data on the Vital Signs in these two visits do not match. If confirmed the visits occurred on the same day, the data must match. Please review and reconcile. Thank you' answered with 'Entered Day 209 VS' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 21:23:08
User opened query 'Visit 4 Day 209 and Visit OL-D57 are both dated 19Mar2021. However, the data on the Vital Signs in these two visits do not match. If confirmed the visits occurred on the same day, the data must match. Please review and reconcile. Thank you' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 01:25:33
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Mar 2021 19:59:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Mar 2021 15:21:31

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:53
User signature succeeded.	Cynthia Gay (b) (4)	19 Mar 2021 19:59:42
User entered '19 Mar 2021'	(b) (4), (b) (6)	19 Mar 2021 15:21:31

US3692001
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:06
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:53
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Mar 2021 19:59:42
User entered '09:32'	(b) (4), (b) (6)	19 Mar 2021 15:21:31

US3692001
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:06
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:53
User entered '19 Mar 2021 09:32'	System	19 Mar 2021 15:21:31

US3692001
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:06
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:53
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Mar 2021 19:59:42
User entered '36.9' C	(b) (4), (b) (6)	19 Mar 2021 15:21:31

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:53
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Mar 2021 19:59:42
User entered 'Oral (Oral)'	(b) (4), (b) (6)	19 Mar 2021 15:21:31

US3692001
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:06
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:53
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Mar 2021 19:59:42
User entered empty.	(b) (4), (b) (6)	19 Mar 2021 15:21:31

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:53
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Mar 2021 19:59:42
User entered '73'	(b) (4), (b) (6)	19 Mar 2021 15:21:31

US3692001
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:06
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:53
User entered 'bpm'	System	19 Mar 2021 15:21:31

US3692001

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:24:06

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:53
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Mar 2021 19:59:42
User entered '16'	(b) (4), (b) (6)	19 Mar 2021 15:21:31

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:53
User entered 'breaths/min'	System	19 Mar 2021 15:21:31

FDA-CBER-2022-1614-3323203

US3692001
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:06

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:53
User signature succeeded.	Cynthia Gay (b) (4)	19 Mar 2021 19:59:42
User entered '124'	(b) (4), (b) (6)	19 Mar 2021 15:21:31

US3692001
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:06
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:53
User entered 'mmHg'	System	19 Mar 2021 15:21:31

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:53
User signature succeeded.	Cynthia Gay (b) (4)	19 Mar 2021 19:59:42
User entered '81'	(b) (4), (b) (6)	19 Mar 2021 15:21:31

FDA-CBER-2022-1614-3323206

US3692001
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:06
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:53
User entered 'mmHg'	System	19 Mar 2021 15:21:31

US3692001
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:06
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:53

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:53

US3692001

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:24:06

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:53
User signature succeeded.	Cynthia Gay (b) (4)	19 Mar 2021 19:59:42
User entered 'No (N)'	(b) (4), (b) (6)	19 Mar 2021 15:21:38

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:53
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Mar 2021 19:59:42
User entered empty.	(b) (4), (b) (6)	19 Mar 2021 15:21:38

US3692001

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:24:06

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:53
User signature succeeded.	Cynthia Gay (b) (4)	19 Mar 2021 19:59:42
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Mar 2021 15:21:54

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:53
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Mar 2021 19:59:42
User entered '19 Mar 2021'	(b) (4), (b) (6)	19 Mar 2021 15:21:54

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:53
User signature succeeded.	Cynthia Gay (b) (4)	19 Mar 2021 19:59:42
User entered '09:44'	(b) (4), (b) (6)	19 Mar 2021 15:21:54

FDA-CBER-2022-1614-3323214

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:11:53
User entered '19 Mar 2021 09:44'	System	19 Mar 2021 15:21:54

FDA-CBER-2022-1614-3323215

US3692001
Folder: Adverse Events
Form: Adverse Events Summary
Generated On: 10 Jun 2021 09:24:06

Did the participant experience any adverse events?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:15:47
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
DataPoint Un-verified.	(b) (4), (b) (6)	22 Jan 2021 20:34:20
DataPoint Verified.	(b) (4), (b) (6)	22 Jan 2021 20:34:18
User entered 'Yes (Y)'	Kristi Kirkland (b) (4) (b) (4)	02 Sep 2020 22:18:01

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:27:44

Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:27:44
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User closed query 'Per MM: Please confirm if this subject was assessed for potential COVID-19 per Section 8.1.2 ' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 05:39:31
User closed query 'Per DM CLR: Please review if this sign/symptom should be combined with AE #2 (SINUS CONGESTION), as these have overlapping start/stop dates. Review if these AEs are related and if so combine into one medical condition. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 05:39:29
Query 'Per MM: Please confirm if this subject was assessed for potential COVID-19 per Section 8.1.2 ' answered with 'Confirmed, subject was assessed. ' (Site from DM).	Mandy Tipton (b) (4) (b) (4)	23 Sep 2020 23:27:39
Query 'Per DM CLR: Please review if this sign/symptom should be combined with AE #2 (SINUS CONGESTION), as these have overlapping start/stop dates. Review if these AEs are related and if so combine into one medical condition. Update eCRF as appropriate. ' answered with 'Considered separate AE's.' (Site from DM).	Mandy Tipton (b) (4) (b) (4)	23 Sep 2020 23:23:21
User opened query 'Per MM: Please confirm if this subject was assessed for potential COVID-19 per Section 8.1.2 ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 17:55:52
User opened query 'Per DM CLR: Please review if this sign/symptom should be combined with AE #2 (SINUS CONGESTION), as these have overlapping start/stop dates. Review if these AEs are related and if so combine into one medical condition. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 11:43:13

US3692001

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:24:06

Adverse event

Audit	User	Time (GMT)
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory tract signs and symptoms, HLT: Upper respiratory tract signs and symptoms, PT: Sneezing, LLT: Sneezing - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 22:24:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 22:24:50
Data point term sent to Coder	System	02 Sep 2020 22:24:39
User entered 'Sneezing'	Kristi Kirkland (b) (4) (b) (4)	02 Sep 2020 22:24:02

US3692001
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:24:06
Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:27:44
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'No (N)'	Kristi Kirkland (b) (4) (b) (4)	02 Sep 2020 22:24:02

US3692001

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:24:06

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:27:44
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'No (N)'	Kristi Kirkland (b) (4) (b) (4)	02 Sep 2020 22:24:02

US3692001
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:24:06
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:27:44
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'No (N)'	Kristi Kirkland (b) (4) (b) (4)	02 Sep 2020 22:24:02

US3692001

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:24:06

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:27:44
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '28 Aug 2020'	Kristi Kirkland (b) (4) (b) (4)	02 Sep 2020 22:24:02

US3692001

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:24:06

Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:27:44
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	02 Sep 2020 22:25:39
User entered empty; reason for change Data Entry Error	Kristi Kirkland (b) (4) (b) (4)	02 Sep 2020 22:25:39
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	02 Sep 2020 22:24:02
User entered '00:00'	Kristi Kirkland (b) (4) (b) (4)	02 Sep 2020 22:24:02

US3692001

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:24:06

AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:27:44
User entered empty.	System	02 Sep 2020 22:25:39
User entered '28 Aug 2020 00:00'	System	02 Sep 2020 22:24:02

US3692001
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:24:06
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:27:44
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'No (N)'	Kristi Kirkland (b) (4) (b) (4)	02 Sep 2020 22:24:02

US3692001
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:24:06
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:27:44
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '1 Sep 2020'	Kristi Kirkland (b) (4) (b) (4)	02 Sep 2020 22:24:02

US3692001
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:24:06

End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:27:44
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered empty.	Kristi Kirkland (b) (4) (b) (4)	02 Sep 2020 22:24:02

AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:27:44
User entered empty.	System	02 Sep 2020 22:24:02

FDA-CBER-2022-1614-3323229

US3692001
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:24:06
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:27:44
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'Grade 1/Mild (Grade 1/Mild)'	Kristi Kirkland (b) (4) (b) (4)	02 Sep 2020 22:24:02

US3692001
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:24:06
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:27:44
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'No (N)'	Kristi Kirkland (b) (4) (b) (4)	02 Sep 2020 22:24:02

US3692001
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:24:06
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:27:44
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '0'	Kristi Kirkland (b) (4) (b) (4)	02 Sep 2020 22:24:02

US3692001

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:24:06

Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:27:44
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '0'	Kristi Kirkland (b) (4) (b) (4)	02 Sep 2020 22:24:02

US3692001

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:24:06

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:27:44
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	02 Sep 2020 22:25:55
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).	System	02 Sep 2020 22:25:55
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	02 Sep 2020 22:24:02
User entered '0'	Kristi Kirkland (b) (4) (b) (4)	02 Sep 2020 22:24:02

US3692001

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:24:06

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:27:44
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered empty.	Kristi Kirkland (b) (4) (b) (4)	02 Sep 2020 22:24:02

US3692001

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:24:06

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:27:44
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered empty.	Kristi Kirkland (b) (4) (b) (4)	02 Sep 2020 22:24:02

US3692001

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:24:06

Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:27:44
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered empty; reason for change Data Entry Error	Kristi Kirkland (b) (4) (b) (4)	02 Sep 2020 22:25:55
User entered 'No (N)'	Kristi Kirkland (b) (4) (b) (4)	02 Sep 2020 22:24:02

US3692001
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:24:06

Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:27:44
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered empty.	Kristi Kirkland (b) (4) (b) (4)	02 Sep 2020 22:24:02

US3692001

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:24:06

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:27:44
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '0'	Kristi Kirkland (b) (4) (b) (4)	02 Sep 2020 22:24:02

US3692001

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:24:06

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:27:44
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '0'	Kristi Kirkland (b) (4) (b) (4)	02 Sep 2020 22:24:02

US3692001

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:24:06

Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:27:44
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '0'	Kristi Kirkland (b) (4) (b) (4)	02 Sep 2020 22:24:02

US3692001
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:24:06
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:27:44
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'Not Related (NOT RELATED)'	Kristi Kirkland (b) (4) (b) (4)	02 Sep 2020 22:24:02

US3692001
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:24:06
Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:27:44
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'Not Related (NOT RELATED)'	Kristi Kirkland (b) (4) (b) (4)	02 Sep 2020 22:24:02

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:24:06

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:27:44
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'None (NONE)'	Kristi Kirkland (b) (4) (b) (4)	02 Sep 2020 22:24:02

US3692001
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:24:06
None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:27:44
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	02 Sep 2020 22:25:39
User entered '1' reason for change: Data Entry Error	Kristi Kirkland (b) (4) (b) (4)	02 Sep 2020 22:25:39
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	02 Sep 2020 22:24:02
User entered '0'	Kristi Kirkland (b) (4) (b) (4)	02 Sep 2020 22:24:02

US3692001

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:24:06

Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:27:44
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '0'	Kristi Kirkland (b) (4) (b) (4)	02 Sep 2020 22:24:02

US3692001

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:24:06

Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:27:44
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '0'	Kristi Kirkland (b) (4) (b) (4)	02 Sep 2020 22:24:02

US3692001

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:24:06

Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:27:44
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Kristi Kirkland (b) (4) (b) (4)	02 Sep 2020 22:24:02

US3692001

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:24:06

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:27:44
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered empty.	Kristi Kirkland (b) (4) (b) (4)	02 Sep 2020 22:24:02

US3692001
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:24:06
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:27:44
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered empty.	Kristi Kirkland (b) (4) (b) (4)	02 Sep 2020 22:24:02

US3692001
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:24:06
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:27:44
User entered '0'	System	02 Sep 2020 22:24:02

US3692001
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:24:06
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:27:44
User entered '0'	System	02 Sep 2020 22:24:02

US3692001
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:24:06
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:27:44
User entered '0'	System	02 Sep 2020 22:24:02

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:07

US3692001
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:24:06
Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:07
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Upper respiratory tract disorders (excl infections), HLT: Paranasal sinus disorders (excl infections and neoplasms), PT: Sinus congestion, LLT: Sinus congestion - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Feb 2021 00:04:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Feb 2021 00:04:04
Data point term sent to Coder	System	19 Feb 2021 23:32:11
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User closed query 'Per MM: Please confirm if this subject was assessed for potential COVID-19 per Section 8.1.2 ' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 05:39:24
Query 'Per MM: Please confirm if this subject was assessed for potential COVID-19 per Section 8.1.2 ' answered with 'Confirmed, subject was assessed. ' (Site from DM).	Mandy Tipton (b) (4) (b) (4)	23 Sep 2020 23:27:28
User opened query 'Per MM: Please confirm if this subject was assessed for potential COVID-19 per Section 8.1.2 ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 17:53:06
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Upper respiratory tract disorders (excl infections), HLT: Paranasal sinus disorders (excl infections and neoplasms), PT: Sinus congestion, LLT: Sinus congestion - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 01:09:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 01:09:43
Data point term sent to Coder	System	04 Sep 2020 01:09:05
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Upper respiratory tract disorders (excl infections), HLT: Paranasal sinus disorders (excl infections and neoplasms), PT: Sinus congestion, LLT: Sinus congestion - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 01:08:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 01:08:42

US3692001

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:24:06

Adverse event

Audit	User	Time (GMT)
User closed query 'CDM-Coding: For coding purpose, please provide the body location to the term, and update the term accordingly.' (Site from System).	System	04 Sep 2020 01:08:09
Query 'CDM-Coding: For coding purpose, please provide the body location to the term, and update the term accordingly.' answered with 'Updated. ' (Site from System).	Mandy Tipton (b) (4) (b) (4)	04 Sep 2020 01:08:09
Data point term sent to Coder	System	04 Sep 2020 01:08:04
User entered 'sinus CONGESTION' reason for change: Data Entry Error	Mandy Tipton (b) (4) (b) (4)	04 Sep 2020 01:08:01
User opened query 'CDM-Coding: For coding purpose, please provide the body location to the term, and update the term accordingly.' (Site from System).	Coder Import (b) (4) (b) (4)	03 Sep 2020 08:32:33
Data point term sent to Coder	System	02 Sep 2020 22:27:47
User entered 'Congestion'	Kristi Kirkland (b) (4) (b) (4)	02 Sep 2020 22:27:01

US3692001

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:24:06

Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'No (N)'	Kristi Kirkland (b) (4) (b) (4)	02 Sep 2020 22:27:01

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'No (N)'	Kristi Kirkland (b) (4) (b) (4)	02 Sep 2020 22:27:01

FDA-CBER-2022-1614-3323258

US3692001

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:24:06

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'No (N)'	Kristi Kirkland (b) (4) (b) (4)	02 Sep 2020 22:27:01

US3692001
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:24:06

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '28 Aug 2020'	Kristi Kirkland (b) (4) (b) (4)	02 Sep 2020 22:27:01

US3692001
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:24:06

Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered empty.	Kristi Kirkland (b) (4) (b) (4)	02 Sep 2020 22:27:01

US3692001

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:24:06

AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:07
User entered empty.	System	02 Sep 2020 22:27:01

US3692001
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:24:06
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'No (N)'	Kristi Kirkland (b) (4) (b) (4)	02 Sep 2020 22:27:01

US3692001

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:24:06

If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '1 Sep 2020'	Kristi Kirkland (b) (4) (b) (4)	02 Sep 2020 22:27:01

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered empty.	Kristi Kirkland (b) (4) (b) (4)	02 Sep 2020 22:27:01

FDA-CBER-2022-1614-3323265

US3692001

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:24:06

AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:07
User entered empty.	System	02 Sep 2020 22:27:01

US3692001
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:24:06
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Sep 2020 22:27:29
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Sep 2020 22:27:29
User entered 'Grade 1/Mild (Grade 1/Mild)' reason for change: Data Entry Error	Kristi Kirkland (b) (4) (b) (4)	02 Sep 2020 22:27:29
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Sep 2020 22:27:01
User entered empty.	Kristi Kirkland (b) (4) (b) (4)	02 Sep 2020 22:27:01

US3692001
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:24:06
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'No (N)'	Kristi Kirkland (b) (4) (b) (4)	02 Sep 2020 22:27:01

US3692001

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:24:06

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '0'	Kristi Kirkland (b) (4) (b) (4)	02 Sep 2020 22:27:01

US3692001

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:24:06

Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '0'	Kristi Kirkland (b) (4) (b) (4)	02 Sep 2020 22:27:01

US3692001

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:24:06

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '0'	Kristi Kirkland (b) (4) (b) (4)	02 Sep 2020 22:27:01

Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:24:06

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered empty.	Kristi Kirkland (b) (4) (b) (4)	02 Sep 2020 22:27:01

US3692001
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:24:06

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered empty.	Kristi Kirkland (b) (4) (b) (4)	02 Sep 2020 22:27:01

US3692001
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:24:06
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered empty.	Kristi Kirkland (b) (4) (b) (4)	02 Sep 2020 22:27:01

US3692001
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:24:06
Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered empty.	Kristi Kirkland (b) (4) (b) (4)	02 Sep 2020 22:27:01

US3692001

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:24:06

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '0'	Kristi Kirkland (b) (4) (b) (4)	02 Sep 2020 22:27:01

US3692001

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:24:06

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '0'	Kristi Kirkland (b) (4) (b) (4)	02 Sep 2020 22:27:01

US3692001
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:24:06
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '0'	Kristi Kirkland (b) (4) (b) (4)	02 Sep 2020 22:27:01

US3692001

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:24:06

Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Sep 2020 22:27:29
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Sep 2020 22:27:29
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Kristi Kirkland (b) (4) (b) (4)	02 Sep 2020 22:27:29
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Sep 2020 22:27:01
User entered empty.	Kristi Kirkland (b) (4) (b) (4)	02 Sep 2020 22:27:01

US3692001

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:24:06

Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Sep 2020 22:27:29
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Sep 2020 22:27:29
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Kristi Kirkland (b) (4) (b) (4)	02 Sep 2020 22:27:29
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Sep 2020 22:27:01
User entered empty.	Kristi Kirkland (b) (4) (b) (4)	02 Sep 2020 22:27:01

US3692001
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:24:06
Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'None (NONE)'	Kristi Kirkland (b) (4) (b) (4)	02 Sep 2020 22:27:01

US3692001
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:24:06
None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '1'	Kristi Kirkland (b) (4) (b) (4)	02 Sep 2020 22:27:01

US3692001

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:24:06

Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '0'	Kristi Kirkland (b) (4) (b) (4)	02 Sep 2020 22:27:01

US3692001

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:24:06

Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '0'	Kristi Kirkland (b) (4) (b) (4)	02 Sep 2020 22:27:01

Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:24:06
Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Kristi Kirkland (b) (4) (b) (4)	02 Sep 2020 22:27:01

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered empty.	Kristi Kirkland (b) (4) (b) (4)	02 Sep 2020 22:27:01

FDA-CBER-2022-1614-3323286

US3692001
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:24:06
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:07
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered empty.	Kristi Kirkland (b) (4) (b) (4)	02 Sep 2020 22:27:01

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:07
User entered '0'	System	02 Sep 2020 22:27:01

FDA-CBER-2022-1614-3323288

Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:24:06

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:07
User entered '0'	System	02 Sep 2020 22:27:01

US3692001
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:24:06
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:07

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:15

US3692001
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:24:06
Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:15
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Tachypnoea, LLT: Tachypnea - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Feb 2021 00:04:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Feb 2021 00:04:04
Data point term sent to Coder	System	19 Feb 2021 23:32:11
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User closed query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 17:41:04
Query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' answered with 'Per protocol, the subject was assessed for potential COVID- 19 infection. ' (Site from DM).	Oesa Vinesett (b) (4) (b) (4)	01 Dec 2020 14:33:00
User opened query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 11:50:01
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Tachypnoea, LLT: Tachypnea - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Nov 2020 13:45:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Nov 2020 13:45:49
Data point term sent to Coder	System	14 Nov 2020 13:45:26
User entered 'tachypnea'	Kristi Kirkland (b) (4) (b) (4)	14 Nov 2020 13:45:16

US3692001

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:24:06

Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:15
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'No (N)'	Kristi Kirkland (b) (4) (b) (4)	14 Nov 2020 13:45:16

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:15
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'No (N)'	Kristi Kirkland (b) (4) (b) (4)	14 Nov 2020 13:45:16

FDA-CBER-2022-1614-3323294

US3692001
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:24:06

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:15
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'No (N)'	Kristi Kirkland (b) (4) (b) (4)	14 Nov 2020 13:45:16

US3692001
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:24:06

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:15
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '26 Aug 2020'	Kristi Kirkland (b) (4) (b) (4)	14 Nov 2020 13:45:16

US3692001

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:24:06

Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:15
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User closed query 'Data is required. Please provide.' (Site from System).	System	14 Nov 2020 13:45:29
User entered '17:48' reason for change: Data Entry Error	Kristi Kirkland (b) (4) (b) (4)	14 Nov 2020 13:45:29
User opened query 'Data is required. Please provide.' (Site from System).	System	14 Nov 2020 13:45:16
User entered empty.	Kristi Kirkland (b) (4) (b) (4)	14 Nov 2020 13:45:16

US3692001

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:24:06

AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:15
User entered '26 Aug 2020 17:48'	System	14 Nov 2020 13:45:29
User entered empty.	System	14 Nov 2020 13:45:16

US3692001
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:24:06
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:15
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'No (N)'	Kristi Kirkland (b) (4) (b) (4)	14 Nov 2020 13:45:16

US3692001
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:24:06

If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:15
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '23 Oct 2020'	Kristi Kirkland (b) (4) (b) (4)	14 Nov 2020 13:45:16

US3692001

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:24:06

End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:15
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User closed query 'Data is required. Please provide.' (Site from System).	System	14 Nov 2020 13:45:29
User entered '8:30' reason for change: Data Entry Error	Kristi Kirkland (b) (4) (b) (4)	14 Nov 2020 13:45:29
User opened query 'Data is required. Please provide.' (Site from System).	System	14 Nov 2020 13:45:16
User entered empty.	Kristi Kirkland (b) (4) (b) (4)	14 Nov 2020 13:45:16

US3692001

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:24:06

AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:15
User entered '23 Oct 2020 8:30'	System	14 Nov 2020 13:45:29
User entered empty.	System	14 Nov 2020 13:45:16

US3692001
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:24:06
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:15
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'Grade 1/Mild (Grade 1/Mild)'	Kristi Kirkland (b) (4) (b) (4)	14 Nov 2020 13:45:16

US3692001
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:24:06
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:15
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'No (N)'	Kristi Kirkland (b) (4) (b) (4)	14 Nov 2020 13:45:16

US3692001
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:24:06
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:15
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '0'	Kristi Kirkland (b) (4) (b) (4)	14 Nov 2020 13:45:16

US3692001

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:24:06

Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:15
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '0'	Kristi Kirkland (b) (4) (b) (4)	14 Nov 2020 13:45:16

US3692001

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:24:06

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:15
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '0'	Kristi Kirkland (b) (4) (b) (4)	14 Nov 2020 13:45:16

US3692001

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:24:06

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:15
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered empty.	Kristi Kirkland (b) (4) (b) (4)	14 Nov 2020 13:45:16

US3692001
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:24:06

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:15
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered empty.	Kristi Kirkland (b) (4) (b) (4)	14 Nov 2020 13:45:16

US3692001
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:24:06
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:15
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered empty.	Kristi Kirkland (b) (4) (b) (4)	14 Nov 2020 13:45:16

US3692001

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:24:06

Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:15
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered empty.	Kristi Kirkland (b) (4) (b) (4)	14 Nov 2020 13:45:16

US3692001

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:24:06

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:15
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '0'	Kristi Kirkland (b) (4) (b) (4)	14 Nov 2020 13:45:16

US3692001

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:24:06

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:15
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '0'	Kristi Kirkland (b) (4) (b) (4)	14 Nov 2020 13:45:16

US3692001
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:24:06
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:15
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '0'	Kristi Kirkland (b) (4) (b) (4)	14 Nov 2020 13:45:16

Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:15
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'Not Related (NOT RELATED)'	Kristi Kirkland (b) (4) (b) (4)	14 Nov 2020 13:45:16

FDA-CBER-2022-1614-3323315

US3692001
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:24:06
Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:15
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'Not Related (NOT RELATED)'	Kristi Kirkland (b) (4) (b) (4)	14 Nov 2020 13:45:16

US3692001

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:24:06

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:15
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'None (NONE)'	Kristi Kirkland (b) (4) (b) (4)	14 Nov 2020 13:45:16

US3692001

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:24:06

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:15
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '1'	Kristi Kirkland (b) (4) (b) (4)	14 Nov 2020 13:45:16

US3692001
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:24:06
Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:15
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '0'	Kristi Kirkland (b) (4) (b) (4)	14 Nov 2020 13:45:16

US3692001

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:24:06

Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:15
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '0'	Kristi Kirkland (b) (4) (b) (4)	14 Nov 2020 13:45:16

US3692001
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:24:06
Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:15
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Kristi Kirkland (b) (4) (b) (4)	14 Nov 2020 13:45:16

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:24:06

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:15
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered empty.	Kristi Kirkland (b) (4) (b) (4)	14 Nov 2020 13:45:16

US3692001
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:24:06
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:15
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered empty.	Kristi Kirkland (b) (4) (b) (4)	14 Nov 2020 13:45:16

US3692001

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:24:06

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:15
User entered '0'	System	14 Nov 2020 13:45:16

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:15
User entered '0'	System	14 Nov 2020 13:45:16

US3692001
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:24:06
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:15

US3692001

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:24:06

AEID

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 17:46:16
User entered 'USA-US123-2020-mRNA-1273-P301000004'	System	21 Dec 2020 17:46:12
User entered 'New'	(b) (4), (b) (6)	21 Dec 2020 17:46:12

US3692001
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:24:06
Adverse event

Audit	User	Time (GMT)
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal ulceration and perforation, HLT: Gastric ulcers and perforation, PT: Gastric ulcer haemorrhage, LLT: Bleeding gastric ulcer - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Feb 2021 00:03:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Feb 2021 00:03:59
Data point term sent to Coder	System	19 Feb 2021 23:32:11
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal ulceration and perforation, HLT: Gastric ulcers and perforation, PT: Gastric ulcer haemorrhage, LLT: Bleeding gastric ulcer - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Dec 2020 21:56:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Dec 2020 21:56:56
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal ulceration and perforation, HLT: Gastric ulcers and perforation, PT: Gastric ulcer haemorrhage, LLT: Bleeding gastric ulcer - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Dec 2020 21:33:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Dec 2020 21:33:44
Data point term sent to Coder	System	21 Dec 2020 20:09:48
Coding entries removed.	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 20:09:20
User entered 'BLEEDING Gastric ULCER' reason for change: Data Entry Error	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 20:09:20
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal ulceration and perforation, HLT: Peptic ulcers and perforation, PT: Peptic ulcer haemorrhage, LLT: Bleeding peptic ulcer - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Dec 2020 00:32:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Dec 2020 00:32:42
Data point term sent to Coder	System	19 Dec 2020 00:31:43
User entered 'bleeding peptic ulcer'	Mandy Tipton (b) (4) (b) (4)	19 Dec 2020 00:30:54

US3692001

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:24:06

Was this a medically-attended AE?

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'Yes (Y)'	Mandy Tipton (b) (4) (b) (4)	19 Dec 2020 00:30:54

US3692001

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:24:06

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'No (N)'	Mandy Tipton (b) (4) (b) (4)	19 Dec 2020 00:30:54

US3692001
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:24:06
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'No (N)'	Mandy Tipton (b) (4) (b) (4)	19 Dec 2020 00:30:54

US3692001

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:24:06

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '14 Dec 2020'	Mandy Tipton (b) (4) (b) (4)	19 Dec 2020 00:30:54

US3692001
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:24:06

Start time *(00:00-23:59)*

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered empty.	Mandy Tipton (b) (4) (b) (4)	19 Dec 2020 00:30:54

US3692001

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:24:06

AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	19 Dec 2020 00:30:54

US3692001

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:24:06

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'No (N)'	Mandy Tipton (b) (4) (b) (4)	19 Dec 2020 00:30:54

US3692001
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:24:06
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '16 Dec 2020'	Mandy Tipton (b) (4) (b) (4)	19 Dec 2020 00:30:54

US3692001

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:24:06

End time *(00:00-23:59)*

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered empty.	Mandy Tipton (b) (4) (b) (4)	19 Dec 2020 00:30:54

US3692001

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:24:06

AE End Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	19 Dec 2020 00:30:54

US3692001
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:24:06
Severity

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'Grade 3/Severe (Grade 3/Severe)'	Mandy Tipton (b) (4) (b) (4)	19 Dec 2020 00:30:54

US3692001

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:24:06

Is the adverse event serious?

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'Yes (Y)'	Mandy Tipton (b) (4) (b) (4)	19 Dec 2020 00:30:54

US3692001
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:24:06
Death

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '0'	Mandy Tipton (b) (4) (b) (4)	19 Dec 2020 00:30:54

US3692001

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:24:06

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '0'	Mandy Tipton (b) (4) (b) (4)	19 Dec 2020 00:30:54

US3692001
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:24:06
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '1'	Mandy Tipton (b) (4) (b) (4)	19 Dec 2020 00:30:54

US3692001

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:24:06

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '14 Dec 2020'	Mandy Tipton (b) (4) (b) (4)	19 Dec 2020 00:30:54

US3692001

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:24:06

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '16 Dec 2020'	Mandy Tipton (b) (4) (b) (4)	19 Dec 2020 00:30:54

US3692001
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:24:06
Admitted to ICU?

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'No (N)'	Mandy Tipton (b) (4) (b) (4)	19 Dec 2020 00:30:54

US3692001

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:24:06

Number of Days in ICU

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered empty.	Mandy Tipton (b) (4) (b) (4)	19 Dec 2020 00:30:54

US3692001

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:24:06

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '0'	Mandy Tipton (b) (4) (b) (4)	19 Dec 2020 00:30:54

US3692001

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:24:06

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '0'	Mandy Tipton (b) (4) (b) (4)	19 Dec 2020 00:30:54

US3692001

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:24:06

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '0'	Mandy Tipton (b) (4) (b) (4)	19 Dec 2020 00:30:54

US3692001
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:24:06
Relationship to investigational product

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'Not Related (NOT RELATED)'	Mandy Tipton (b) (4) (b) (4)	19 Dec 2020 00:30:54

US3692001

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:24:06

Relationship to Study Procedure

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'Not Related (NOT RELATED)'	Mandy Tipton (b) (4) (b) (4)	19 Dec 2020 00:30:54

US3692001

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:24:06

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'Not Applicable (NOT APPLICABLE)'	Mandy Tipton (b) (4) (b) (4)	19 Dec 2020 00:30:54

US3692001
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:24:06

None

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '0'	Mandy Tipton (b) (4) (b) (4)	19 Dec 2020 00:30:54

US3692001

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:24:06

Concomitant Medication

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '1'	Mandy Tipton (b) (4) (b) (4)	19 Dec 2020 00:30:54

US3692001
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:24:06
Concomitant Procedure

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User closed query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 16:28:05
Query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' answered with 'it is the EDG that happened on Dec14, there will be another beginning of Feb' (Site from DM).	Kristi Kirkland (b) (4) (b) (4)	23 Jan 2021 01:33:25
User opened query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 10:35:11
User entered '1'	Mandy Tipton (b) (4) (b) (4)	19 Dec 2020 00:30:54

US3692001

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:24:06

Outcome

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Mandy Tipton (b) (4) (b) (4)	19 Dec 2020 00:30:54

US3692001

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:24:06

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered empty.	Mandy Tipton (b) (4) (b) (4)	19 Dec 2020 00:30:54

US3692001
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:24:06
Narrative

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User closed query 'PV Query: Was the subject tested for COVID-19? If yes, please provide results.' (Site from Safety).	(b) (4), (b) (6)	28 Dec 2020 22:03:03
Query 'PV Query: Was the subject tested for COVID-19? If yes, please provide results.' answered with 'Narrative updated with result. ' (Site from Safety).	Mandy Tipton (b) (4) (b) (4)	23 Dec 2020 20:07:25
User entered 'PARTICIPANT PRESENTED TO ER WITH HEMATEMESIS ON 14DEC2020. AN EGD WAS CONDUCTED REVEALING A BLEEDING ULCER. NO CAUSE WAS IDENTIFIED. THE BLEEDING WAS STABILIZED AND THE PARTICIPANT WAS DISCHARGED ON 16DEC2020. CONCOMITANT MEDICATIONS AND PROCEDURES WILL BE UPDATED ONCE OSH RECORDS ARE RECEIVED. UPDATE: MR RECEIVED AND EDC UPDATED ACCORDINGLY. Result of negative was provided for a COVID-19 test, but the specimen and test type were not provided.' reason for change: New Information	Mandy Tipton (b) (4) (b) (4)	23 Dec 2020 20:07:15
User opened query 'PV Query: Was the subject tested for COVID-19? If yes, please provide results.' (Site from Safety).	(b) (4), (b) (6)	23 Dec 2020 14:48:36
User entered 'PARTICIPANT PRESENTED TO ER WITH HEMATEMESIS ON 14DEC2020. AN EGD WAS CONDUCTED REVEALING A BLEEDING ULCER. NO CAUSE WAS IDENTIFIED. THE BLEEDING WAS STABILIZED AND THE PARTICIPANT WAS DISCHARGED ON 16DEC2020. CONCOMITANT MEDICATIONS AND PROCEDURES WILL BE UPDATED ONCE OSH RECORDS ARE RECEIVED. Update: MR received and EDC updated accordingly.' reason for change: New Information	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 20:55:59

US3692001

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:24:06

Narrative

Audit	User	Time (GMT)
User entered 'Participant presented to ER with hematemesis on 14DEC2020. An EGD was conducted revealing a bleeding ulcer. No cause was identified. The bleeding was stabilized and the participant was discharged on 16DEC2020. Concomitant medications and procedures will be updated once OSH records are received.'	Mandy Tipton (b) (4) (b) (4)	19 Dec 2020 00:30:54

US3692001
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:24:06
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '1'	System	19 Dec 2020 00:30:54

US3692001

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:24:06

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	19 Dec 2020 00:30:54

US3692001

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:24:06

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	19 Dec 2020 00:30:54

US3692001
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:24:06
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:19

US3692001
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:24:06
Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:19
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Feb 2021 00:04:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Feb 2021 00:04:03
Data point term sent to Coder	System	19 Feb 2021 23:32:11
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Dec 2020 21:33:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Dec 2020 21:33:48
Data point term sent to Coder	System	21 Dec 2020 21:09:03
User entered 'Headache'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:08:09

US3692001
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:24:06
Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:19
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'No (N)'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:08:09

US3692001
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:24:06

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:19
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'No (N)'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:08:09

US3692001
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:24:06
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:19
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'No (N)'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:08:09

US3692001
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:24:06

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:19
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '11 Dec 2020'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:08:09

US3692001
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:24:06

Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:19
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered empty.	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:08:09

US3692001
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:24:06
AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:19
User entered empty.	System	21 Dec 2020 21:08:09

US3692001

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:24:06

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:19
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'No (N)'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:08:09

US3692001

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:24:06

If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:19
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '11 Dec 2020'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:08:09

US3692001
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:24:06

End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:19
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered empty.	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:08:09

US3692001
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:24:06
AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:19
User entered empty.	System	21 Dec 2020 21:08:09

US3692001

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:24:06

Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:19
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'Grade 1/Mild (Grade 1/Mild)'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:08:09

US3692001
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:24:06
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:19
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'No (N)'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:08:09

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:19
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '0'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:08:09

FDA-CBER-2022-1614-3323378

US3692001
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:24:06
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:19
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '0'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:08:09

US3692001

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:24:06

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:19
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '0'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:08:09

US3692001

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:24:06

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:19
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered empty.	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:08:09

US3692001

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:24:06

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:19
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered empty.	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:08:09

US3692001
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:24:06
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:19
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered empty.	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:08:09

US3692001

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:24:06

Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:19
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered empty.	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:08:09

US3692001

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:24:06

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:19
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '0'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:08:09

US3692001

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:24:06

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:19
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '0'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:08:09

US3692001

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:24:06

Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:19
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '0'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:08:09

US3692001
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:24:06
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:19
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'Not Related (NOT RELATED)'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:08:09

US3692001
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:24:06
Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:19
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'Not Related (NOT RELATED)'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:08:09

US3692001

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:24:06

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:19
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'Not Applicable (NOT APPLICABLE)'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:08:09

US3692001
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:24:06
None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:19
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '0'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:08:09

US3692001

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:24:06

Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:19
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '1'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:08:09

US3692001
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:24:06
Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:19
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '0'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:08:09

US3692001
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:24:06
Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:19
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:08:09

US3692001

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:24:06

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:19
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered empty.	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:08:09

US3692001
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:24:06
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:19
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered empty.	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:08:09

US3692001
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:24:06
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:19
User entered '0'	System	21 Dec 2020 21:08:09

US3692001

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:24:06

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:19
User entered '0'	System	21 Dec 2020 21:08:09

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:24:06

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:19

US3692001
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 10 Jun 2021 09:24:06
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:23

US3692001

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:24:06

Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:23
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal inflammatory conditions, HLT: Oesophagitis (excl infective), PT: Eosinophilic oesophagitis, LLT: Eosinophilic esophagitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Feb 2021 00:19:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Feb 2021 00:19:58
Data point term sent to Coder	System	19 Feb 2021 23:32:10
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal inflammatory conditions, HLT: Oesophagitis (excl infective), PT: Eosinophilic oesophagitis, LLT: Eosinophilic esophagitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Dec 2020 21:33:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Dec 2020 21:33:49
Data point term sent to Coder	System	21 Dec 2020 21:11:07
User entered 'Eosinophilic Esophagitis'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:10:49

US3692001
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 10 Jun 2021 09:24:06
Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:23
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'No (N)'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:10:49

US3692001

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:24:06

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:23
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'No (N)'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:10:49

US3692001

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:24:06

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:23
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'No (N)'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:10:49

US3692001
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 10 Jun 2021 09:24:06

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:23
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '14 Dec 2020'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:10:49

US3692001
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 10 Jun 2021 09:24:06

Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:23
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered empty.	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:10:49

US3692001

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:24:06

AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:23
User entered empty.	System	21 Dec 2020 21:10:49

US3692001
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 10 Jun 2021 09:24:06
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:23
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'No (N)' reason for change: New Information	Maria Stetson (b) (4) (b) (4)	08 Feb 2021 20:21:23
User entered 'Yes (Y)'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:10:49

US3692001
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 10 Jun 2021 09:24:06
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:23
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '18 Jan 2021' reason for change: New Information	Maria Stetson (b) (4) (b) (4)	08 Feb 2021 20:21:23
User entered empty.	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:10:49

US3692001

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:24:06

End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:23
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered empty.	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:10:49

US3692001

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:24:06

AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:23
User entered empty.	System	21 Dec 2020 21:10:49

US3692001
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 10 Jun 2021 09:24:06
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:23
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:10:49

US3692001
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 10 Jun 2021 09:24:06
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:23
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'No (N)'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:10:49

US3692001
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 10 Jun 2021 09:24:06
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:23
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '0'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:10:49

US3692001

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:24:06

Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:23
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '0'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:10:49

US3692001

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:24:06

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:23
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '0'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:10:49

US3692001
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 10 Jun 2021 09:24:06

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:23
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered empty.	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:10:49

US3692001

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:24:06

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:23
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered empty.	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:10:49

US3692001
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 10 Jun 2021 09:24:06
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:23
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered empty.	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:10:49

US3692001
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 10 Jun 2021 09:24:06

Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:23
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered empty.	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:10:49

US3692001

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:24:06

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:23
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '0'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:10:49

US3692001

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:24:06

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:23
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '0'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:10:49

US3692001

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:24:06

Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:23
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '0'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:10:49

US3692001

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:24:06

Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:23
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'Not Related (NOT RELATED)'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:10:49

US3692001

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:24:06

Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:23
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'Not Related (NOT RELATED)'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:10:49

US3692001

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:24:06

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:23
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'Not Applicable (NOT APPLICABLE)'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:10:49

US3692001

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:24:06

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:23
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '0'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:10:49

US3692001

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:24:06

Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:23
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '1'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:10:49

US3692001
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 10 Jun 2021 09:24:06
Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:23
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '0'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:10:49

US3692001
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 10 Jun 2021 09:24:06
Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:23
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Maria Stetson (b) (4) (b) (4)	08 Feb 2021 20:21:23
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:10:49

US3692001
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 10 Jun 2021 09:24:06
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:23
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered empty.	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:10:49

US3692001
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 10 Jun 2021 09:24:06
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:23
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered empty.	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:10:49

FDA-CBER-2022-1614-3323432

US3692001

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:24:06

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:23
User entered '0'	System	21 Dec 2020 21:10:49

US3692001

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:24:06

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:23
User entered '0'	System	21 Dec 2020 21:10:49

Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 10 Jun 2021 09:24:06
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:23

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:28

US3692001

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:24:06

Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:28
User closed query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 10:56:09
Query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' answered with 'Ppt was assessed for COVID-19 infection' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 15:17:12
User opened query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 14:59:38
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Tachypnoea, LLT: Tachypnea - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Feb 2021 00:04:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Feb 2021 00:04:01
Data point term sent to Coder	System	19 Feb 2021 23:32:11
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Tachypnoea, LLT: Tachypnea - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Feb 2021 20:24:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Feb 2021 20:24:40
Data point term sent to Coder	System	08 Feb 2021 20:24:05
User entered 'Tachypnea'	Maria Stetson (b) (4) (b) (4)	08 Feb 2021 20:23:58

US3692001

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:24:06

Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:28
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'No (N)'	Maria Stetson (b) (4) (b) (4)	08 Feb 2021 20:23:58

US3692001
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 10 Jun 2021 09:24:06

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:28
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'No (N)'	Maria Stetson (b) (4) (b) (4)	08 Feb 2021 20:23:58

US3692001

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:24:06

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:28
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'No (N)'	Maria Stetson (b) (4) (b) (4)	08 Feb 2021 20:23:58

US3692001
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 10 Jun 2021 09:24:06

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:28
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '08 Feb 2021'	Maria Stetson (b) (4) (b) (4)	08 Feb 2021 20:23:58

FDA-CBER-2022-1614-3323441

US3692001
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 10 Jun 2021 09:24:06

Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:28
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '12:29'	Maria Stetson (b) (4) (b) (4)	08 Feb 2021 20:23:58

US3692001

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:24:06

AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:28
User entered '08 Feb 2021 12:29'	System	08 Feb 2021 20:23:58

US3692001

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:24:06

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:28
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	01 Apr 2021 21:15:33
User closed query 'Per MM, please provide the end date.' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 11:14:58
Query 'Per MM, please provide the end date.' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 18:49:53
Signature has been broken.	(b) (4), (b) (6)	29 Mar 2021 18:47:06
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	29 Mar 2021 18:47:06
User opened query 'Per MM, please provide the end date.' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 14:59:46
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'Yes (Y)'	Maria Stetson (b) (4) (b) (4)	08 Feb 2021 20:23:58

US3692001
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 10 Jun 2021 09:24:06
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:28
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	01 Apr 2021 21:15:33
Signature has been broken.	(b) (4), (b) (6)	29 Mar 2021 18:47:06
User entered '19 Mar 2021' reason for change: New Information	(b) (4), (b) (6)	29 Mar 2021 18:47:06
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered empty.	Maria Stetson (b) (4) (b) (4)	08 Feb 2021 20:23:58

US3692001

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:24:06

End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:28
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	01 Apr 2021 21:15:33
User closed query 'Data is required. Please provide.' (Site from System).	System	29 Mar 2021 18:49:38
Signature has been broken.	(b) (4), (b) (6)	29 Mar 2021 18:49:38
User entered '09:32' reason for change: New Information	(b) (4), (b) (6)	29 Mar 2021 18:49:38
User opened query 'Data is required. Please provide.' (Site from System).	System	29 Mar 2021 18:47:06
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered empty.	Maria Stetson (b) (4) (b) (4)	08 Feb 2021 20:23:58

US3692001

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:24:06

AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:28
User entered '19 Mar 2021 09:32'	System	29 Mar 2021 18:49:38
User entered empty.	System	08 Feb 2021 20:23:58

US3692001
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 10 Jun 2021 09:24:06
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:28
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'Grade 1/Mild (Grade 1/Mild)'	Maria Stetson (b) (4) (b) (4)	08 Feb 2021 20:23:58

US3692001
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 10 Jun 2021 09:24:06
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:28
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'No (N)'	Maria Stetson (b) (4) (b) (4)	08 Feb 2021 20:23:58

FDA-CBER-2022-1614-3323449

US3692001
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 10 Jun 2021 09:24:06
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:28
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '0'	Maria Stetson (b) (4) (b) (4)	08 Feb 2021 20:23:58

US3692001

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:24:06

Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:28
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '0'	Maria Stetson (b) (4) (b) (4)	08 Feb 2021 20:23:58

US3692001

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:24:06

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:28
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '0'	Maria Stetson (b) (4) (b) (4)	08 Feb 2021 20:23:58

US3692001

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:24:06

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:28
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered empty.	Maria Stetson (b) (4) (b) (4)	08 Feb 2021 20:23:58

US3692001

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:24:06

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:28
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered empty.	Maria Stetson (b) (4) (b) (4)	08 Feb 2021 20:23:58

Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:28
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered empty.	Maria Stetson (b) (4) (b) (4)	08 Feb 2021 20:23:58

US3692001

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:24:06

Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:28
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered empty.	Maria Stetson (b) (4) (b) (4)	08 Feb 2021 20:23:58

US3692001

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:24:06

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:28
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '0'	Maria Stetson (b) (4) (b) (4)	08 Feb 2021 20:23:58

US3692001

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:24:06

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:28
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '0'	Maria Stetson (b) (4) (b) (4)	08 Feb 2021 20:23:58

US3692001

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:24:06

Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:28
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '0'	Maria Stetson (b) (4) (b) (4)	08 Feb 2021 20:23:58

US3692001
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 10 Jun 2021 09:24:06
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:28
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'Not Related (NOT RELATED)'	Maria Stetson (b) (4) (b) (4)	08 Feb 2021 20:23:58

US3692001
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 10 Jun 2021 09:24:06
Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:28
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'Not Related (NOT RELATED)'	Maria Stetson (b) (4) (b) (4)	08 Feb 2021 20:23:58

US3692001

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:24:06

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:28
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	08 Apr 2021 14:22:33
User closed query 'Per CDM: Please review the "Action taken with investigational product" field since the AE started after the subject was dosed at the OL-D1 and before Exposure (12:54) at the OL-D29 visit. Review and update as appropriate as per CCGs. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 16:32:52
Query 'Per CDM: Please review the "Action taken with investigational product" field since the AE started after the subject was dosed at the OL-D1 and before Exposure (12:54) at the OL-D29 visit. Review and update as appropriate as per CCGs. ' answered with 'Updated.' (Site from DM).	Maria Stetson (b) (4) (b) (4)	06 Apr 2021 17:57:36
Signature has been broken.	Maria Stetson (b) (4) (b) (4)	06 Apr 2021 17:57:17
User entered 'None (NONE)' reason for change: Per Query Resolution	Maria Stetson (b) (4) (b) (4)	06 Apr 2021 17:57:17
User opened query 'Per CDM: Please review the "Action taken with investigational product" field since the AE started after the subject was dosed at the OL-D1 and before Exposure (12:54) at the OL-D29 visit. Review and update as appropriate as per CCGs. ' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 08:14:36
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'Not Applicable (NOT APPLICABLE)'	Maria Stetson (b) (4) (b) (4)	08 Feb 2021 20:23:58

US3692001

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:24:06

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:28
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '1'	Maria Stetson (b) (4) (b) (4)	08 Feb 2021 20:23:58

US3692001

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:24:06

Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:28
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '0'	Maria Stetson (b) (4) (b) (4)	08 Feb 2021 20:23:58

US3692001

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:24:06

Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:28
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '0'	Maria Stetson (b) (4) (b) (4)	08 Feb 2021 20:23:58

US3692001
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 10 Jun 2021 09:24:06
Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:28
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	01 Apr 2021 21:15:33
Signature has been broken.	(b) (4), (b) (6)	29 Mar 2021 18:47:06
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Mar 2021 18:47:06
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Maria Stetson (b) (4) (b) (4)	08 Feb 2021 20:23:58

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:24:06

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:28
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered empty.	Maria Stetson (b) (4) (b) (4)	08 Feb 2021 20:23:58

US3692001
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 10 Jun 2021 09:24:06
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:28
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered empty.	Maria Stetson (b) (4) (b) (4)	08 Feb 2021 20:23:58

US3692001

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:24:06

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:28
User entered '0'	System	08 Feb 2021 20:23:58

US3692001

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:24:06

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:28
User entered '0'	System	08 Feb 2021 20:23:58

US3692001

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:24:06

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:28:28

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:24:06

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:15:47
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'Yes (Y)'	Abigail Riddick (b) (4) (b) (4)	31 Aug 2020 13:14:01

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:24:06

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: SIMVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Feb 2021 00:04:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Feb 2021 00:04:01
Data point term sent to Coder	System	19 Feb 2021 23:32:12
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: SIMVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Dec 2020 18:50:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Dec 2020 18:50:51
Data point term sent to Coder	System	22 Dec 2020 18:49:41
Coding entries removed.	Erin Cardot (b) (4) (b) (4)	22 Dec 2020 18:49:23
User entered 'SIMVaSTATIN' reason for change: Data Entry Error	Erin Cardot (b) (4) (b) (4)	22 Dec 2020 18:49:23
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: SIMVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 13:19:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 13:19:51
Data point term sent to Coder	System	31 Aug 2020 13:19:00
User entered 'simvistatin'	Abigail Riddick (b) (4) (b) (4)	31 Aug 2020 13:18:00

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:24:06

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'No (N)'	Abigail Riddick (b) (4) (b) (4)	31 Aug 2020 13:18:00

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:24:06

Indication

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'hyperlipidemia'	Abigail Riddick (b) (4) (b) (4)	31 Aug 2020 13:18:00

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:24:06

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '10'	Abigail Riddick (b) (4) (b) (4)	31 Aug 2020 13:18:00

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:24:06

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'mg (mg)'	Abigail Riddick (b) (4) (b) (4)	31 Aug 2020 13:18:00

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:24:06

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered empty.	Abigail Riddick (b) (4) (b) (4)	31 Aug 2020 13:18:00

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:24:06

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'once daily (QD)'	Abigail Riddick (b) (4) (b) (4)	31 Aug 2020 13:18:00

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:24:06

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered empty.	Abigail Riddick (b) (4) (b) (4)	31 Aug 2020 13:18:00

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:24:06

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'Oral (ORAL)'	Abigail Riddick (b) (4) (b) (4)	31 Aug 2020 13:18:00

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:24:06

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered empty.	Abigail Riddick (b) (4) (b) (4)	31 Aug 2020 13:18:00

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:24:06

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'un UNK 2016'	Abigail Riddick (b) (4) (b) (4)	31 Aug 2020 13:18:00

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:24:06

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '0'	Abigail Riddick (b) (4) (b) (4)	31 Aug 2020 13:18:00

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:24:06

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Sep 2020 19:44:16
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Sep 2020 19:44:16
User entered 'Yes (Y)' reason for change: Data Entry Error	Mandy Tipton (b) (4) (b) (4)	01 Sep 2020 19:44:16
User opened query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 13:18:00
User entered empty.	Abigail Riddick (b) (4) (b) (4)	31 Aug 2020 13:18:00

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:24:06

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered empty.	Abigail Riddick (b) (4) (b) (4)	31 Aug 2020 13:18:00

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:24:06

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'No (N)'	Abigail Riddick (b) (4) (b) (4)	31 Aug 2020 13:18:00

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:24:06

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 13:18:00

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:24:06

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 13:18:00

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:24:06

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Aug 2020 13:18:00

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:24:06

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ANDROGENS, ATC: 3-OXOANDROSTEN (4) DERIVATIVES, PRODUCT: TESTOSTERONE CIPIONATE, PRODUCTSYNONYM: TESTOSTERONE CYPIONATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Feb 2021 00:03:58
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Feb 2021 00:03:58
Data point term sent to Coder	System	19 Feb 2021 23:32:12
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ANDROGENS, ATC: 3-OXOANDROSTEN (4) DERIVATIVES, PRODUCT: TESTOSTERONE CIPIONATE, PRODUCTSYNONYM: TESTOSTERONE CYPIONATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 13:21:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 13:21:46
Data point term sent to Coder	System	31 Aug 2020 13:21:02
User entered 'testosterone cypionate'	Abigail Riddick (b) (4) (b) (4)	31 Aug 2020 13:20:40

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:24:06

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'No (N)'	Abigail Riddick (b) (4) (b) (4)	31 Aug 2020 13:20:40

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:24:06

Indication

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'low testosterone'	Abigail Riddick (b) (4) (b) (4)	31 Aug 2020 13:20:40

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:24:06

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '200'	Abigail Riddick (b) (4) (b) (4)	31 Aug 2020 13:20:40

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:24:06

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'mg (mg)'	Abigail Riddick (b) (4) (b) (4)	31 Aug 2020 13:20:40

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered empty.	Abigail Riddick (b) (4) (b) (4)	31 Aug 2020 13:20:40

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:24:06

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'other (OTHER)'	Abigail Riddick (b) (4) (b) (4)	31 Aug 2020 13:20:40

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:24:06

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'every two weeks'	Abigail Riddick (b) (4) (b) (4)	31 Aug 2020 13:20:40

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:24:06

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'Intramuscular (INTRAMUSCULAR)'	Abigail Riddick (b) (4) (b) (4)	31 Aug 2020 13:20:40

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:24:06
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered empty.	Abigail Riddick (b) (4) (b) (4)	31 Aug 2020 13:20:40

FDA-CBER-2022-1614-3323500

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:24:06

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'un UNK 2016'	Abigail Riddick (b) (4) (b) (4)	31 Aug 2020 13:20:40

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:24:06

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '0'	Abigail Riddick (b) (4) (b) (4)	31 Aug 2020 13:20:40

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:24:06

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Sep 2020 19:44:04
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Sep 2020 19:44:04
User entered 'Yes (Y)' reason for change: Data Entry Error	Mandy Tipton (b) (4) (b) (4)	01 Sep 2020 19:44:04
User opened query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 13:20:40
User entered empty.	Abigail Riddick (b) (4) (b) (4)	31 Aug 2020 13:20:40

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:24:06

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered empty.	Abigail Riddick (b) (4) (b) (4)	31 Aug 2020 13:20:40

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:24:06

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'No (N)'	Abigail Riddick (b) (4) (b) (4)	31 Aug 2020 13:20:40

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:24:06

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 13:20:40

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:24:06

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 13:20:40

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:24:06

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 13:20:40

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:24:06

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:51:40
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Feb 2021 00:04:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Feb 2021 00:04:02
Data point term sent to Coder	System	19 Feb 2021 23:32:11
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Nov 2020 13:24:05
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Nov 2020 13:24:05
Data point term sent to Coder	System	18 Nov 2020 13:23:26
User entered 'Flu vaccine'	Erin Cardot (b) (4) (b) (4)	18 Nov 2020 13:23:17

FDA-CBER-2022-1614-3323509

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:24:06

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:51:40
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'Yes (Y)'	Erin Cardot (b) (4) (b) (4)	18 Nov 2020 13:23:17

FDA-CBER-2022-1614-3323510

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:24:06

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:51:40
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'Prophylaxis for flu'	Erin Cardot (b) (4) (b) (4)	18 Nov 2020 13:23:17

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:24:06

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:51:40
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '.5'	Erin Cardot (b) (4) (b) (4)	18 Nov 2020 13:23:17

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:24:06
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:51:40
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'mL (mL)'	Erin Cardot (b) (4) (b) (4)	18 Nov 2020 13:23:17

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:24:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:51:40
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered empty.	Erin Cardot (b) (4) (b) (4)	18 Nov 2020 13:23:17

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:24:06

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:51:40
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'once (ONCE)'	Erin Cardot (b) (4) (b) (4)	18 Nov 2020 13:23:17

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:24:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:51:40
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered empty.	Erin Cardot (b) (4) (b) (4)	18 Nov 2020 13:23:17

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:24:06

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:51:40
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'Intramuscular (INTRAMUSCULAR)'	Erin Cardot (b) (4) (b) (4)	18 Nov 2020 13:23:17

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:24:06

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:51:40
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered empty.	Erin Cardot (b) (4) (b) (4)	18 Nov 2020 13:23:17

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:24:06

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:51:40
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'UN Nov 2020'	Erin Cardot (b) (4) (b) (4)	18 Nov 2020 13:23:17

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:24:06

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:51:40
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '0'	Erin Cardot (b) (4) (b) (4)	18 Nov 2020 13:23:17

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:24:06

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:51:40
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'No (N)'	Erin Cardot (b) (4) (b) (4)	18 Nov 2020 13:23:17

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:24:06

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:51:40
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'UN Nov 2020'	Erin Cardot (b) (4) (b) (4)	18 Nov 2020 13:23:17

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:24:06

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:51:40
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'No (N)'	Erin Cardot (b) (4) (b) (4)	18 Nov 2020 13:23:17

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:24:06

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:51:40
User entered empty.	System	18 Nov 2020 13:23:17

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:24:06

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:51:40
User entered empty.	System	18 Nov 2020 13:23:17

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:24:06

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:51:40
User entered empty.	System	18 Nov 2020 13:23:17

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:24:06

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:30
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Feb 2021 00:04:03
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Feb 2021 00:04:03
Data point term sent to Coder	System	19 Feb 2021 23:32:12
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Jan 2021 15:19:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Jan 2021 15:19:00
Data point term sent to Coder	System	21 Dec 2020 20:59:43
User entered 'Pantoprazole'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 20:59:28

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:24:06

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:30
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'No (N)'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 20:59:28

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:24:06

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:30
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'Gastric Ulcer/Eosinophilic Esophagitis'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 20:59:28

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:24:06

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:30
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '40'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 20:59:28

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:24:06

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:30
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'mg (mg)'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 20:59:28

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:24:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:30
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered empty.	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 20:59:28

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:24:06

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:30
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'twice daily (BID)'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 20:59:28

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:24:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:30
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered empty.	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 20:59:28

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:24:06

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:30
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'Oral (ORAL)'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 20:59:28

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:24:06

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:30
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered empty.	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 20:59:28

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:24:06

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:30
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '16 Dec 2020'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 20:59:28

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:24:06

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:30
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '0'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 20:59:28

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:24:06

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:30
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'No (N)' reason for change: New Information	Maria Stetson (b) (4) (b) (4)	08 Feb 2021 18:47:43
User entered 'Yes (Y)'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 20:59:28

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:24:06

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:30
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '04 Jan 2021' reason for change: New Information	Maria Stetson (b) (4) (b) (4)	08 Feb 2021 18:47:43
User entered empty.	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 20:59:28

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:24:06

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:30
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'No (N)'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 20:59:28

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:24:06

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:30
User entered '2'	System	21 Dec 2020 20:59:28

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:24:06

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:30
User entered '1'	System	21 Dec 2020 20:59:28

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:24:06

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:30
User entered '804 (804)'	System	21 Dec 2020 20:59:28

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:24:06

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:34
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: ANTACIDS, ATC: CALCIUM COMPOUNDS, PRODUCT: CALCIUM CARBONATE, PRODUCTSYNONYM: TUMS [CALCIUM CARBONATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Feb 2021 00:04:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Feb 2021 00:04:02
Data point term sent to Coder	System	19 Feb 2021 23:32:14
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: ANTACIDS, ATC: CALCIUM COMPOUNDS, PRODUCT: CALCIUM CARBONATE, PRODUCTSYNONYM: TUMS [CALCIUM CARBONATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Feb 2021 08:52:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Feb 2021 08:52:44
Data point term sent to Coder	System	09 Feb 2021 20:48:29
Coding entries removed.	Maria Stetson (b) (4) (b) (4)	09 Feb 2021 20:47:45
User entered 'TUMS (Calcium Carbonate)' reason for change: New Information	Maria Stetson (b) (4) (b) (4)	09 Feb 2021 20:47:45
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: ANTACIDS, ATC: CALCIUM COMPOUNDS, PRODUCT: CALCIUM CARBONATE, PRODUCTSYNONYM: TUMS [CALCIUM CARBONATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Dec 2020 21:33:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Dec 2020 21:33:48
Data point term sent to Coder	System	21 Dec 2020 21:01:45

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:24:06

Name of Medication

Audit	User	Time (GMT)
User entered 'Tums'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:00:50

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:24:06

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:34
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'No (N)'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:00:50

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:24:06

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:34
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'GERD'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:00:50

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:24:06

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:34
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 16:17:42
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'Dosage provided.' (Site from DM).	Maria Stetson (b) (4) (b) (4)	09 Feb 2021 20:47:52
User entered '750' reason for change: New Information	Maria Stetson (b) (4) (b) (4)	09 Feb 2021 20:47:45
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 09:14:46
User entered '1'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:00:50

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:24:06

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:34
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'mg (mg)' reason for change: New Information	Maria Stetson (b) (4) (b) (4)	09 Feb 2021 20:47:45
User entered 'tablet (TABLET)'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:00:50

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:24:06
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:34
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered empty.	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:00:50

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:24:06

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:34
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'as needed (PRN)'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:00:50

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:24:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:34
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered empty.	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:00:50

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:24:06

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:34
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'Oral (ORAL)'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:00:50

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:24:06

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:34
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered empty.	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:00:50

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:24:06

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:34
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'UN Jan 2018'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:00:50

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:24:06

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:34
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '0'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:00:50

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:24:06

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:34
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'No (N)'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:00:50

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:24:06

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:34
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '16 Dec 2020'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:00:50

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:24:06

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:34
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'No (N)'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:00:50

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:24:06

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:34
User entered empty.	System	21 Dec 2020 21:00:50

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:24:06

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:34
User entered empty.	System	21 Dec 2020 21:00:50

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:24:06

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:34
User entered empty.	System	21 Dec 2020 21:00:50

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:24:06

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:39
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: SALICYLIC ACID AND DERIVATIVES, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Feb 2021 00:04:05
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Feb 2021 00:04:05
Data point term sent to Coder	System	19 Feb 2021 23:32:14
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: SALICYLIC ACID AND DERIVATIVES, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Dec 2020 21:33:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Dec 2020 21:33:47
Data point term sent to Coder	System	21 Dec 2020 21:02:47
Data point term sent to Coder	System	21 Dec 2020 21:01:45
User entered 'Aspirin'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:01:36

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:24:06

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:39
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'No (N)'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:01:36

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:24:06

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:39
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Dec 2020 21:01:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Dec 2020 21:01:53
User entered 'Headache' reason for change: Data Entry Error	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:01:53
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Dec 2020 21:01:36
User entered empty.	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:01:36

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:24:06

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:39
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '81'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:01:36

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:24:06

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:39
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'mg (mg)'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:01:36

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:24:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:39
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered empty.	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:01:36

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:24:06

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:39
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'once (ONCE)'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:01:36

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:24:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:39
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered empty.	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:01:36

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:24:06

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:39
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'Oral (ORAL)'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:01:36

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:24:06

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:39
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered empty.	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:01:36

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:24:06

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:39
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '11 Dec 2020'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:01:36

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:24:06

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:39
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '0'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:01:36

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:24:06

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:39
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'No (N)'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:01:36

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:24:06

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:39
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '11 Dec 2020'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:01:36

FDA-CBER-2022-1614-3323577

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:24:06

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:39
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'No (N)'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:01:36

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:24:06

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:39
User entered empty.	System	21 Dec 2020 21:01:36

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:24:06

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:39
User entered empty.	System	21 Dec 2020 21:01:36

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:24:06

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:39
User entered empty.	System	21 Dec 2020 21:01:36

FDA-CBER-2022-1614-3323581

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:24:06

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:43
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 14:17:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 14:17:49
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Feb 2021 00:04:05
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Feb 2021 00:04:05
Data point term sent to Coder	System	19 Feb 2021 23:32:12
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Dec 2020 19:00:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Dec 2020 19:00:42
Data point term sent to Coder	System	21 Dec 2020 21:03:48
User entered 'Sodium Chloride'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:03:33

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:24:06

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:43
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'No (N)'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:03:33

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:24:06

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:43
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'Gastric ulcer'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:03:33

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:24:06

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:43
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '100'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:03:33

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:24:06

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:43
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'mL (mL)'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:03:33

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:24:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:43
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered empty.	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:03:33

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:24:06

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:43
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'other (OTHER)'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:03:33

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:24:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:43
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'per hour'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:03:33

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:24:06

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:43
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'Intravenous (INTRAVENOUS)'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:03:33

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:24:06

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:43
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered empty.	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:03:33

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:24:06

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:43
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '14 Dec 2020'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:03:33

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:24:06

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:43
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '0'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:03:33

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:24:06

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:43
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'No (N)'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:03:33

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:24:06

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:43
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '15 Dec 2020'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:03:33

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:24:06

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:43
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'No (N)'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:03:33

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:24:06

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:43
User entered empty.	System	21 Dec 2020 21:03:33

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:24:06

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:43
User entered empty.	System	21 Dec 2020 21:03:33

FDA-CBER-2022-1614-3323598

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:24:06

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:43
User entered empty.	System	21 Dec 2020 21:03:33

FDA-CBER-2022-1614-3323599

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:24:06

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:47
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Feb 2021 00:04:03
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Feb 2021 00:04:03
Data point term sent to Coder	System	19 Feb 2021 23:32:14
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Dec 2020 18:14:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Dec 2020 18:14:40
Data point term sent to Coder	System	21 Dec 2020 21:04:51
User entered 'Zofran'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:04:43

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:24:06

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:47
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'No (N)'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:04:43

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:24:06

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:47
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'Gastric ulcer'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:04:43

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:24:06

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:47
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'unk'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:04:43

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:24:06

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:47
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'Other (OTHER)'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:04:43

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:24:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:47
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'Unknown dosage'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:04:43

FDA-CBER-2022-1614-3323605

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:24:06

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:47
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'as needed (PRN)'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:04:43

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:24:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:47
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered empty.	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:04:43

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:24:06

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:47
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'Intravenous (INTRAVENOUS)'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:04:43

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:24:06

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:47
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered empty.	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:04:43

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:24:06

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:47
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '14 Dec 2020'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:04:43

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:24:06

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:47
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '0'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:04:43

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:24:06

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:47
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'No (N)'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:04:43

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:24:06

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:47
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '15 Dec 2020'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:04:43

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:24:06

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:47
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'No (N)'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:04:43

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:24:06

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:47
User entered empty.	System	21 Dec 2020 21:04:43

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:24:06

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:47
User entered empty.	System	21 Dec 2020 21:04:43

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:24:06

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:47
User entered empty.	System	21 Dec 2020 21:04:43

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:24:06

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:52
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE, PRODUCTSYNONYM: PRILOSEC [OMEPRAZOLE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Feb 2021 00:04:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Feb 2021 00:04:00
Data point term sent to Coder	System	19 Feb 2021 23:32:12
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE, PRODUCTSYNONYM: PRILOSEC [OMEPRAZOLE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Dec 2020 18:19:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Dec 2020 18:19:41
Data point term sent to Coder	System	22 Dec 2020 18:51:45
User entered 'Prilosec (omeprazole)'	Erin Cardot (b) (4) (b) (4)	22 Dec 2020 18:50:59

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:24:06

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:52
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'No (N)'	Erin Cardot (b) (4) (b) (4)	22 Dec 2020 18:50:59

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:24:06

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:52
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'Gastric ulcer'	Erin Cardot (b) (4) (b) (4)	22 Dec 2020 18:50:59

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:24:06

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:52
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '40'	Erin Cardot (b) (4) (b) (4)	22 Dec 2020 18:50:59

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:24:06

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:52
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'mg (mg)'	Erin Cardot (b) (4) (b) (4)	22 Dec 2020 18:50:59

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:24:06

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:52
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered empty.	Erin Cardot (b) (4) (b) (4)	22 Dec 2020 18:50:59

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:24:06

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:52
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'twice daily (BID)'	Erin Cardot (b) (4) (b) (4)	22 Dec 2020 18:50:59

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:24:06

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:52
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered empty.	Erin Cardot (b) (4) (b) (4)	22 Dec 2020 18:50:59

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:24:06

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:52
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'Oral (ORAL)'	Erin Cardot (b) (4) (b) (4)	22 Dec 2020 18:50:59

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:24:06

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:52
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered empty.	Erin Cardot (b) (4) (b) (4)	22 Dec 2020 18:50:59

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:24:06

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:52
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '16 Dec 2020'	Erin Cardot (b) (4) (b) (4)	22 Dec 2020 18:50:59

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:24:06

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:52
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '0'	Erin Cardot (b) (4) (b) (4)	22 Dec 2020 18:50:59

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:24:06

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:52
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'No (N)' reason for change: New Information	Maria Stetson (b) (4) (b) (4)	08 Feb 2021 18:45:42
User entered 'Yes (Y)'	Erin Cardot (b) (4) (b) (4)	22 Dec 2020 18:50:59

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:24:06

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:52
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '18 Jan 2021' reason for change: New Information	Maria Stetson (b) (4) (b) (4)	08 Feb 2021 18:45:42
User entered empty.	Erin Cardot (b) (4) (b) (4)	22 Dec 2020 18:50:59

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:24:06

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:52
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'No (N)'	Erin Cardot (b) (4) (b) (4)	22 Dec 2020 18:50:59

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:52
User entered '2'	System	22 Dec 2020 18:50:59

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:24:06

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:52
User entered '1'	System	22 Dec 2020 18:50:59

US3692001

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:24:06

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:01:52
User entered '804 (804)'	System	22 Dec 2020 18:50:59

US3692001

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:24:06

Were any concomitant procedures performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:15:47
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'Yes (Y)'	Erin Cardot (b) (4) (b) (4)	21 Dec 2020 21:52:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	21 Dec 2020 21:50:44
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	04 Nov 2020 15:05:58

US3692001

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:24:06

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '14 Dec 2020'	Erin Cardot (b) (4) (b) (4)	22 Dec 2020 18:46:45

US3692001

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:24:06

Procedure/Surgery

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'Esophagogastroduodenoscopy (EGD)'	Erin Cardot (b) (4) (b) (4)	22 Dec 2020 18:46:45

US3692001

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:24:06

Indication

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered 'Adverse Event (AE)'	Erin Cardot (b) (4) (b) (4)	22 Dec 2020 18:46:45

US3692001

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:24:06

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered empty.	Erin Cardot (b) (4) (b) (4)	22 Dec 2020 18:46:45

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:32:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 17:46:44
User entered 'USA-US123-2020-MRNA-1273-P301000004'	System	21 Dec 2020 17:46:12

FDA-CBER-2022-1614-3323641

US3692001
Folder: SAE USA-US123-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:06
Serious

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:32:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 17:46:44
User entered 'Yes (Y)'	System	21 Dec 2020 17:46:12

Death

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 17:46:44
User entered 'No (N)'	System	21 Dec 2020 17:46:12

US3692001
Folder: SAE USA-US123-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:06
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:32:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 17:46:44
User entered 'No (N)'	System	21 Dec 2020 17:46:12

US3692001
Folder: SAE USA-US123-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:06
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:32:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 17:46:44
User entered 'Yes (Y)'	System	21 Dec 2020 17:46:12

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 17:46:44
User entered 'No (N)'	System	21 Dec 2020 17:46:12

FDA-CBER-2022-1614-3323646

US3692001
Folder: SAE USA-US123-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:06
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 17:46:44
User entered 'No (N)'	System	21 Dec 2020 17:46:12

US3692001
Folder: SAE USA-US123-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:06
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 17:46:44
User entered 'No (N)'	System	21 Dec 2020 17:46:12

US3692001
Folder: SAE USA-US123-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:06

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:32:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 17:46:44
User entered 'Cynthia'	System	21 Dec 2020 17:46:12

US3692001
Folder: SAE USA-US123-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:06
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:32:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 17:46:44
User entered 'Gay'	System	21 Dec 2020 17:46:12

US3692001
Folder: SAE USA-US123-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:06
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:32:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 17:46:44
User entered '130 Mason Farm Rd, CB #7030'	System	21 Dec 2020 17:46:12

US3692001
Folder: SAE USA-US123-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:06
Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:32:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 17:46:44
User entered 'Chapel Hill'	System	21 Dec 2020 17:46:12

US3692001
Folder: SAE USA-US123-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:06
Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
Un-reviewed for Safety.	System	28 Dec 2020 22:03:35
User entered empty.	System	28 Dec 2020 22:03:35
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 22:03:21
User entered 'North Carolina'	Mandy Tipton (b) (4) (b) (4)	23 Dec 2020 20:05:49

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:32:10
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 17:46:44
User entered '27599-7030'	System	21 Dec 2020 17:46:12

US3692001
Folder: SAE USA-US123-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:06
Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:32:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 14:28:31
User entered 'US'	System	21 Dec 2020 17:46:50

US3692001
Folder: SAE USA-US123-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:06
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '3'	System	28 Dec 2020 22:03:35
User entered '2'	System	22 Dec 2020 14:28:58
User entered '1'	System	21 Dec 2020 17:46:50

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 17:46:44
User entered 'USA-US123-2020-MRNA-1273-P301000004'	System	21 Dec 2020 17:46:12

US3692001
Folder: SAE USA-US123-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:06
Serious

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 17:46:44
User entered 'Yes (Y)'	System	21 Dec 2020 17:46:12

Death

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 17:46:44
User entered 'No (N)'	System	21 Dec 2020 17:46:12

FDA-CBER-2022-1614-3323659

US3692001
Folder: SAE USA-US123-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:06
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:32:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 17:46:44
User entered 'No (N)'	System	21 Dec 2020 17:46:12

US3692001
Folder: SAE USA-US123-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:06
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:32:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 17:46:44
User entered 'Yes (Y)'	System	21 Dec 2020 17:46:12

US3692001
Folder: SAE USA-US123-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:06

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:32:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 17:46:44
User entered 'No (N)'	System	21 Dec 2020 17:46:12

US3692001
Folder: SAE USA-US123-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:06
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:32:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 17:46:44
User entered 'No (N)'	System	21 Dec 2020 17:46:12

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:32:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 17:46:44
User entered 'No (N)'	System	21 Dec 2020 17:46:12

FDA-CBER-2022-1614-3323664

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:32:10
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 17:46:44
User entered 'Cynthia'	System	21 Dec 2020 17:46:12

FDA-CBER-2022-1614-3323665

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:32:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 17:46:44
User entered 'Gay'	System	21 Dec 2020 17:46:12

US3692001
Folder: SAE USA-US123-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:06
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 17:46:44
User entered '130 Mason Farm Rd, CB #7030'	System	21 Dec 2020 17:46:12

PRODUCTION RELEASE (v12.003
EAB) (1725)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:32:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 17:46:44
User entered 'Chapel Hill'	System	21 Dec 2020 17:46:12

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
Un-reviewed for Safety.	System	28 Dec 2020 22:03:35
User entered empty.	System	28 Dec 2020 22:03:35
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 22:03:21
User entered 'North Carolina'	Mandy Tipton (b) (4) (b) (4)	23 Dec 2020 20:05:49

US3692001
Folder: SAE USA-US123-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:06
Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:32:10
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 17:46:44
User entered '27599-7030'	System	21 Dec 2020 17:46:12

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:32:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 14:28:31
User entered 'US'	System	21 Dec 2020 17:46:50

US3692001
Folder: SAE USA-US123-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:06
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '3'	System	28 Dec 2020 22:03:35
User entered '2'	System	22 Dec 2020 14:28:58
User entered '1'	System	21 Dec 2020 17:46:50

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '21/Dec/2020 12:46'	System	21 Dec 2020 17:46:50

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:32:10
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 14:28:31
User entered '1'	(b) (4), (b) (6)	21 Dec 2020 17:46:50

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 17:46:44
User entered 'USA-US123-2020-MRNA-1273-P301000004'	System	21 Dec 2020 17:46:12

US3692001
Folder: SAE USA-US123-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:06
Serious

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 17:46:44
User entered 'Yes (Y)'	System	21 Dec 2020 17:46:12

Death

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:32:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 17:46:44
User entered 'No (N)'	System	21 Dec 2020 17:46:12

FDA-CBER-2022-1614-3323677

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:32:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 17:46:44
User entered 'No (N)'	System	21 Dec 2020 17:46:12

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:32:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 17:46:44
User entered 'Yes (Y)'	System	21 Dec 2020 17:46:12

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:32:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 17:46:44
User entered 'No (N)'	System	21 Dec 2020 17:46:12

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:32:10
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 17:46:44
User entered 'No (N)'	System	21 Dec 2020 17:46:12

FDA-CBER-2022-1614-3323681

US3692001
Folder: SAE USA-US123-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:06
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:32:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 17:46:44
User entered 'No (N)'	System	21 Dec 2020 17:46:12

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:32:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 17:46:44
User entered 'Cynthia'	System	21 Dec 2020 17:46:12

FDA-CBER-2022-1614-3323683

US3692001
Folder: SAE USA-US123-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:06
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:32:10
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 17:46:44
User entered 'Gay'	System	21 Dec 2020 17:46:12

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 17:46:44
User entered '130 Mason Farm Rd, CB #7030'	System	21 Dec 2020 17:46:12

US3692001
Folder: SAE USA-US123-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:06
Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 17:46:44
User entered 'Chapel Hill'	System	21 Dec 2020 17:46:12

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
Un-reviewed for Safety.	System	28 Dec 2020 22:03:35
User entered empty.	System	28 Dec 2020 22:03:35
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 22:03:21
User entered 'North Carolina'	Mandy Tipton (b) (4) (b) (4)	23 Dec 2020 20:05:49

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:32:10
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 17:46:44
User entered '27599-7030'	System	21 Dec 2020 17:46:12

US3692001
Folder: SAE USA-US123-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:06

Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:32:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 14:28:31
User entered 'US'	System	21 Dec 2020 17:46:50

US3692001
Folder: SAE USA-US123-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:06
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '3'	System	28 Dec 2020 22:03:35
User entered '2'	System	22 Dec 2020 14:28:58
User entered '1'	System	21 Dec 2020 17:46:50

US3692001

Folder: SAE USA-US123-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:24:06

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '22/Dec/2020 09:28'	System	22 Dec 2020 14:28:58

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:32:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 22:03:21
User entered '1'	(b) (4), (b) (6)	22 Dec 2020 14:28:58

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:32:10
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 17:46:44
User entered 'USA-US123-2020-MRNA-1273-P301000004'	System	21 Dec 2020 17:46:12

US3692001
Folder: SAE USA-US123-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:06
Serious

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:32:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 17:46:44
User entered 'Yes (Y)'	System	21 Dec 2020 17:46:12

Death

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 17:46:44
User entered 'No (N)'	System	21 Dec 2020 17:46:12

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:32:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 17:46:44
User entered 'No (N)'	System	21 Dec 2020 17:46:12

US3692001
Folder: SAE USA-US123-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:06
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:32:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 17:46:44
User entered 'Yes (Y)'	System	21 Dec 2020 17:46:12

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:32:10
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 17:46:44
User entered 'No (N)'	System	21 Dec 2020 17:46:12

FDA-CBER-2022-1614-3323698

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:32:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 17:46:44
User entered 'No (N)'	System	21 Dec 2020 17:46:12

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:32:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 17:46:44
User entered 'No (N)'	System	21 Dec 2020 17:46:12

FDA-CBER-2022-1614-3323700

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:32:10
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 17:46:44
User entered 'Cynthia'	System	21 Dec 2020 17:46:12

Folder: SAE USA-US123-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:06
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:32:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 17:46:44
User entered 'Gay'	System	21 Dec 2020 17:46:12

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:32:10
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	21 Dec 2020 17:46:44
User entered '130 Mason Farm Rd, CB #7030'	System	21 Dec 2020 17:46:12

US3692001
Folder: SAE USA-US123-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:06
Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:32:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 17:46:44
User entered 'Chapel Hill'	System	21 Dec 2020 17:46:12

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
Un-reviewed for Safety.	System	28 Dec 2020 22:03:35
User entered empty.	System	28 Dec 2020 22:03:35
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 22:03:21
User entered 'North Carolina'	Mandy Tipton (b) (4) (b) (4)	23 Dec 2020 20:05:49

US3692001
Folder: SAE USA-US123-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:06
Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:32:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 17:46:44
User entered '27599-7030'	System	21 Dec 2020 17:46:12

Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4)	19 Feb 2021 23:32:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 14:28:31
User entered 'US'	System	21 Dec 2020 17:46:50

FDA-CBER-2022-1614-3323707

US3692001
Folder: SAE USA-US123-2020-MRNA-1273-P301000004
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:06
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '3'	System	28 Dec 2020 22:03:35
User entered '2'	System	22 Dec 2020 14:28:58
User entered '1'	System	21 Dec 2020 17:46:50

US3692001
Folder: SAE USA-US123-2020-MRNA-1273-P301000004
Form: Safety Report Form (3)
Generated On: 10 Jun 2021 09:24:06
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '28/Dec/2020 22:03'	System	28 Dec 2020 22:03:35

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Gay (b) (4) (b) (4)	19 Feb 2021 23:32:10
User entered '1'	(b) (4), (b) (6)	28 Dec 2020 22:03:35