US3792012 (Prod: Hope Research Institute LLC - Hunt - PPDS)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:48:26

All time stamps listed in this document are displayed in GMT

Participant ID US3792012

mRNA-1273-P301 Completion Guidelines

US3792012

Folder: Screening

Form: Visit Date

Data signed: (b) (4) **01 Apr 2021 20:41:01**

Generated On: 10 Jun 2021 09:48:26

Was this visit performed?	Yes ●
	No ○

Visit date (dd MMM yyyy)	12 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●

Folder OID	SCRN

US3792012

Folder: Screening

Form: Demographics

Data signed: (b) (4) **01 Apr 2021 20:40:18**

Generated On: 10 Jun 2021 09:48:26

Date of Birth (MMM yyyy)	(b) (6) 1948
Age	71
Age Units	YEARS
Age (Derived)	72
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

US3792012

Folder: Screening

Form: Enrollment

Data signed: (b) (4)   **01 Apr 2021 20:40:18**

Generated On: 10 Jun 2021 09:48:26

Date of Informed Consent *(dd MMM yyyy)*	12 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

US3792012

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) **01 Apr 2021 20:40:18**

Generated On: 10 Jun 2021 09:48:26

Did the participant meet all eligibility criteria?   Yes ●

                                                     No ◯

US3792012

Folder: Screening

Form: Medical History Summary

Data signed: [(b) (4)] **01 Apr 2021 20:40:19**

Generated On: 10 Jun 2021 09:48:26

Were any significant conditions reported?   Yes ●

                                                          No ◯

US3792012

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) **01 Apr 2021 20:40:19**

Generated On: 10 Jun 2021 09:48:26

Condition	HYPOTHYRIODISM
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)	

US3792012

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) **01 Apr 2021 20:40:19**

Generated On: 10 Jun 2021 09:48:26

Condition	HYPERTENSION
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)	

US3792012

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) **01 Apr 2021 20:40:19**

Generated On: 10 Jun 2021 09:48:26

Condition	GASTROESOPHAGEAL REFLUX DISEASE
Start date (dd MMM yyyy)	UN UNK 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes ⬤
	No ◯
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	
Stop Year (derived)	

US3792012

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) **01 Apr 2021 20:40:19**

Generated On: 10 Jun 2021 09:48:26

Condition	HERPES SYMPLEX TYPE I
Start date (dd MMM yyyy)	UN UNK 1997
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 1997
Start Year (derived)	1997
Stop Month and Year (derived)	
Stop Year (derived)	

US3792012

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) **01 Apr 2021 20:40:19**

Generated On: 10 Jun 2021 09:48:26

Condition	WART LEFT ARM
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes ◯
	No ⬤
If No, please specify the stop date (dd MMM yyyy)	UN JUL 2020
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	JUL 2020
Stop Year (derived)	2020

US3792012

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) **01 Apr 2021 20:40:19**

Generated On: 10 Jun 2021 09:48:26

Condition	WART RIGHT ARM
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes ◯
	No ⬤
If No, please specify the stop date (dd MMM yyyy)	UN JUL 2020
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	JUL 2020
Stop Year (derived)	2020

Condition	TINNITIS BILATERAL EARS
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Start Year (derived)	2005
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-3380958

US3792012

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) **01 Apr 2021 20:40:19**

Generated On: 10 Jun 2021 09:48:26

Condition	POLYURIA
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)	

US3792012

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) **01 Apr 2021 20:40:19**

Generated On: 10 Jun 2021 09:48:26

Condition	BENIGN PROSTATIC HYPERPLASIA
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)	

US3792012

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) **01 Apr 2021 20:40:19**

Generated On: 10 Jun 2021 09:48:26

Condition	LEFT HAND OSTEOARTHRITIS
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes ●
	No ○
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

US3792012

Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) **01 Apr 2021 20:40:19**

Generated On: 10 Jun 2021 09:48:26

Condition	LEFT HAND PAIN
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes ●
	No ○
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

US3792012

Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) **01 Apr 2021 20:40:19**

Generated On: 10 Jun 2021 09:48:26

Condition	CHRONIC BACK PAIN
Start date (dd MMM yyyy)	UN UNK 2011
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 2011
Start Year (derived)	2011
Stop Month and Year (derived)	
Stop Year (derived)	

US3792012

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) **01 Apr 2021 20:41:01**

Generated On: 10 Jun 2021 09:48:26

Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	12 AUG 2020
Time of assessment *(00:00-23:59)*	09:49 (24 HR)
Vital Signs Date and Time (derived)	12 AUG 2020 09:49
Height *(xxx.x)*	67 in
Weight *(xxx.x)*	212 lb
BMI *(xxx.x)*	33.27332 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)	

US3792012

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) **01 Apr 2021 20:41:01**

Generated On: 10 Jun 2021 09:48:26

Was the physical examination performed?   Yes ●

                                                                            No ○

Date of examination *(dd MMM yyyy)*   12 AUG 2020

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

US3792012

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4)   **01 Apr 2021 20:41:01**

Generated On: 10 Jun 2021 09:48:26

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	VOLUNTEERS AT THE (b) (6) HOSPITAL

Location and Living Circumstances Risk (check all that apply)

No Risk Identified	False
Resides in Nursing Home or Assisted Living Facility	False

US3792012

Folder: Screening

Form: Risk of Exposure

Data signed: ▓ (b) (4) ▓ 01 Apr 2021 20:41:01

Generated On: 10 Jun 2021 09:48:26

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)	True
Resides in a single family home (i.e., detached housing)	False
Other	False
Specify	

US3792012

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) **01 Apr 2021 20:41:01**

Generated On: 10 Jun 2021 09:48:26

Was this visit performed?	Yes ●
	No ○

Visit date (dd MMM yyyy)	12 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●

Folder OID	VISIT1

US3792012

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) **01 Apr 2021 20:41:01**

Generated On: 10 Jun 2021 09:48:26

What was the date of randomization? *(dd MMM yyyy)*	12 AUG 2020
What was the participant's randomization number?	185515

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 ⚫

US3792012
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Data signed: (b) (4) **01 Apr 2021 20:41:01**
Generated On: 10 Jun 2021 09:48:26

Height	ND - Not Done
Weight	ND - Not Done

US3792012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) **01 Apr 2021 20:41:01**

Generated On: 10 Jun 2021 09:48:26

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)*	12 AUG 2020
Time of assessment *(00:00-23:59)*	09:49 (24 HR)
Vital Signs Date and Time (derived)	12 AUG 2020 09:49
Temperature *(xxx.x)*	97.5 F
Route of measurement	Oral ●
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	73 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	111 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	77 mmHg
Diastolic Blood Pressure units	MMHG

US3792012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) **01 Apr 2021 20:41:01**

Generated On: 10 Jun 2021 09:48:26

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)*	12 AUG 2020
Time of assessment *(00:00-23:59)*	11:25 (24 HR)
Vital Signs Date and Time (derived)	12 AUG 2020 11:25
Temperature *(xxx.x)*	97.7 F
Route of measurement	Oral ⬤
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	72 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	83 mmHg
Diastolic Blood Pressure units	MMHG

US3792012

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) **01 Apr 2021 20:41:01**

Generated On: 10 Jun 2021 09:48:26

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.

US3792012

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) **01 Apr 2021 20:41:01**

Generated On: 10 Jun 2021 09:48:26

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)*	12 AUG 2020
What was the treatment time? *(00:00-23:59)*	10:43 (24 HR)
Treatment Date and Time (derived)	12 AUG 2020 10:43
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

US3792012

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) **01 Apr 2021 20:41:01**

Generated On: 10 Jun 2021 09:48:26

Was the sample collected?	Yes ●
	No ○
Collection date *(dd MMM yyyy)*	12 AUG 2020
Collection time *(00:00-23:59)*	09:58 (24 HR)
Collection date and time (derived)	12 AUG 2020 09:58

US3792012

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) **01 Apr 2021 20:41:01**

Generated On: 10 Jun 2021 09:48:26

Collection date *(dd MMM yyyy)*			12 AUG 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:00	12 AUG 2020 10:00
Nasopharyngeal Swab 2	No		

US3792012

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) **01 Apr 2021 20:41:01**

Generated On: 10 Jun 2021 09:48:26

Is the participant continuing to the next visit?   Yes ⬤

                                                                                          No ◯

Continuing Flag   1

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**	97.7 °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	12 AUG 2020 11:27
PC Open Date & Time	12 AUG 2020 11:03
PC Close Date & Time	12 AUG 2020 13:33

TIMEPOINT	DAY 1, AFTER VACCINATION
	(AT HOME)

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

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

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

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

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

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

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

Please record your **TEMPERATURE in °F**	97.1 °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	12 AUG 2020 15:41
PC Open Date & Time	12 AUG 2020 14:28
PC Close Date & Time	13 AUG 2020 11:59

US3792012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:48:26

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**	97.6 °F

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

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

PC Time Stamp	13 AUG 2020 12:22
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3792012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:48:26

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	97.4 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

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

PC Time Stamp	14 AUG 2020 12:01
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

FDA-CBER-2022-1614-3380981

US3792012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:48:26

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**	99.1 °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	15 AUG 2020 12:02
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

FDA-CBER-2022-1614-3380982

US3792012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:48:26

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	97.2 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

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

PC Time Stamp	16 AUG 2020 12:01
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3792012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:48:26

TIMEPOINT	DAY 6

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	97.4 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

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

PC Time Stamp	17 AUG 2020 12:06
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3792012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:48:26

TIMEPOINT	DAY 7

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

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

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

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

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

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

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

Please record your **TEMPERATURE in °F**	97.6 °F

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

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

PC Time Stamp	18 AUG 2020 13:17
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

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	12 AUG 2020 11:28
PC Open Date & Time	12 AUG 2020 11:03
PC Close Date & Time	12 AUG 2020 13:33

US3792012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:48:26

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 ⭕
Please record - **REDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site redness with the ruler provided.	5
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ⬤
	No ⭕
Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site swelling/hardness with the ruler provided.	5
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	12 AUG 2020 15:46
PC Open Date & Time	12 AUG 2020 14:28
PC Close Date & Time	13 AUG 2020 11:59

US3792012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:48:26

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 - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**	2
Measure the largest size across any injection site swelling/hardness with the ruler provided.	

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	13 AUG 2020 12:23
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3792012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:48:26

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 - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**	5
Measure the largest size across any injection site swelling/hardness with the ruler provided.	

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	14 AUG 2020 12:02
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

FDA-CBER-2022-1614-3380989

US3792012
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:48:26

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	15 AUG 2020 12:03
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

FDA-CBER-2022-1614-3380990

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	16 AUG 2020 12:01
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 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	17 AUG 2020 12:06
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3792012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:48:26

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	18 AUG 2020 13:17
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3792012
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:48:26

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 ◯

US3792012

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:48:26

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

PC Time stamp	12 AUG 2020 11:29
PC Open Date & Time	12 AUG 2020 11:03
PC Close Date & Time	12 AUG 2020 13:33

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 ○

US3792012

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:48:26

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ●
	Yes ○
PC Time stamp	12 AUG 2020 15:47
PC Open Date & Time	12 AUG 2020 14:28
PC Close Date & Time	13 AUG 2020 11:59

US3792012
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:48:26

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	13 AUG 2020 12:24
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3792012
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:48:26

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	14 AUG 2020 12:03
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3792012
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:48:26

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	15 AUG 2020 12:03
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3792012

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:48:26

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 ⬤

US3792012
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:48:26

	Yes ◯
PC Time stamp	16 AUG 2020 12:02
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3792012
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:48:26

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	17 AUG 2020 12:07
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3792012
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:48:26

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	18 AUG 2020 13:17
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3792012
Folder: Safety Call Day 8 (1)
Form: Safety Call
Data signed: (b) (4) **01 Apr 2021 20:40:18**
Generated On: 10 Jun 2021 09:48:26

Was Contact Attempted?	Yes ⬤
	No ◯
Date of Contact or Contact Attempt *(dd MMM yyyy)*	20 AUG 2020
Please select one status for the follow-up contact	Contact Made ⬤
	Contact Not Made ◯

Comments

If Contact Not Made, please provide Comments

US3792012

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) **01 Apr 2021 20:40:18**

Generated On: 10 Jun 2021 09:48:26

Is the participant continuing to the next visit?   Yes ●

No ○

Continuing Flag   1

US3792012
Folder: Safety Call Day 15 (1)
Form: Safety Call
Data signed: (b) (4) **01 Apr 2021 20:40:18**
Generated On: 10 Jun 2021 09:48:26

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

| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 26 AUG 2020 |

| Please select one status for the follow-up contact | Contact Made ⬤ |
| | Contact Not Made ◯ |

Comments

If Contact Not Made, please provide Comments

US3792012

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) **01 Apr 2021 20:40:18**

Generated On: 10 Jun 2021 09:48:26

Is the participant continuing to the next visit?   Yes ●

                                                                                    No ○

Continuing Flag   1

US3792012

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) **01 Apr 2021 20:40:18**

Generated On: 10 Jun 2021 09:48:26

| 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

US3792012

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) **01 Apr 2021 20:40:18**

Generated On: 10 Jun 2021 09:48:26

Is the participant continuing to the next visit?   Yes ●

                                                                                                                      No ◯

Continuing Flag   1

US3792012
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Data signed: (b) (4) **01 Apr 2021 20:41:01**
Generated On: 10 Jun 2021 09:48:26

Was this visit performed?	Yes ●
	No ○
Visit date (dd MMM yyyy)	9 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●
Folder OID	VISIT2

US3792012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) **01 Apr 2021 20:41:01**

Generated On: 10 Jun 2021 09:48:26

Timepoint	Pre-Dose ●
	Post-Dose ○
Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	9 SEP 2020
Time of assessment *(00:00-23:59)*	09:02 (24 HR)
Vital Signs Date and Time (derived)	9 SEP 2020 09:02
Temperature *(xxx.x)*	97.9 F
Route of measurement	Oral ●
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	73 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	82 mmHg
Diastolic Blood Pressure units	MMHG

US3792012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) **01 Apr 2021 20:41:01**

Generated On: 10 Jun 2021 09:48:26

Timepoint	Pre-Dose ◯
	Post-Dose ⬤
Were vital signs assessed?	Yes ⬤
	No ◯
Date of assessment *(dd MMM yyyy)*	9 SEP 2020
Time of assessment *(00:00-23:59)*	10:17 (24 HR)
Vital Signs Date and Time (derived)	9 SEP 2020 10:17
Temperature *(xxx.x)*	97.6 F
Route of measurement	Oral ⬤
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	66 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	88 mmHg
Diastolic Blood Pressure units	MMHG

US3792012

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) **01 Apr 2021 20:41:01**

Generated On: 10 Jun 2021 09:48:26

Was the physical examination performed?   Yes ●

No ◯

Date of examination *(dd MMM yyyy)*   9 SEP 2020

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?	MRNA-1273 OR PLACEBO
What was the treatment date? *(dd MMM yyyy)*	9 SEP 2020
What was the treatment time? *(00:00-23:59)*	09:44 (24 HR)
Treatment Date and Time (derived)	9 SEP 2020 09:44
Which arm was used to give treatment?	Left Arm ●
	Right Arm ○
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

FDA-CBER-2022-1614-3381020

Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **01 Apr 2021 20:41:01**
Generated On: 10 Jun 2021 09:48:26

Was the sample collected?	Yes ●
	No ○

Collection date *(dd MMM yyyy)*	9 SEP 2020
Collection time *(00:00-23:59)*	09:06 (24 HR)
Collection date and time (derived)	9 SEP 2020 09:06

Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab
Data signed: (b) (4)   **01 Apr 2021 20:41:01**
Generated On: 10 Jun 2021 09:48:26

Collection date *(dd MMM yyyy)*   9 SEP 2020

Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:09	9 SEP 2020 09:09
Nasopharyngeal Swab 2	No		

US3792012

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) **01 Apr 2021 20:41:01**

Generated On: 10 Jun 2021 09:48:26

Is the participant continuing to the next visit?   Yes ●

No ○

Continuing Flag   1

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**	97.6 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

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

PC Time Stamp	09 SEP 2020 10:25
PC Open Date & Time	09 SEP 2020 10:04
PC Close Date & Time	09 SEP 2020 12:34

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**	97.6 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

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

PC Time Stamp	09 SEP 2020 13:30
PC Open Date & Time	09 SEP 2020 13:29
PC Close Date & Time	10 SEP 2020 11:59

US3792012

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:48:26

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**	97.0 °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	10 SEP 2020 14:28
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3792012
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:48:26

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**	99.7 °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	11 SEP 2020 12:10
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

FDA-CBER-2022-1614-3381027

TIMEPOINT	DAY 4

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	97.8 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	12 SEP 2020 17:39
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3792012

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:48:26

TIMEPOINT	DAY 5

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	97.8 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

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

PC Time Stamp	13 SEP 2020 17:48
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3792012

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:48:26

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	14 SEP 2020 17:33
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

TIMEPOINT	DAY 7

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

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

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

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

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

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

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

Please record your **TEMPERATURE in °F**	97.6 °F

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

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

PC Time Stamp	15 SEP 2020 18:01
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

FDA-CBER-2022-1614-3381031

US3792012

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:48:26

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	09 SEP 2020 10:26
PC Open Date & Time	09 SEP 2020 10:04
PC Close Date & Time	09 SEP 2020 12:34

US3792012

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:48:26

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 - **SWELLING/HARDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site swelling/hardness with the ruler provided.	5

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ⚫
	Does not interfere with activity ⚪
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ⚪
	Any use of prescription pain reliever or prevents daily activity ⚪

PC Time Stamp	09 SEP 2020 13:31
PC Open Date & Time	09 SEP 2020 13:29
PC Close Date & Time	10 SEP 2020 11:59

US3792012
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:48:26

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	10 SEP 2020 14:29
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3792012

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:48:26

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

US3792012
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:48:26

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	12 SEP 2020 17:39
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

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	13 SEP 2020 17:48
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3792012

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:48:26

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	14 SEP 2020 17:33
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 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	15 SEP 2020 18:01
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3792012
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:48:26

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	○

US3792012
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:48:26

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

PC Time stamp	09 SEP 2020 10:27
PC Open Date & Time	09 SEP 2020 10:04
PC Close Date & Time	09 SEP 2020 12:34

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	09 SEP 2020 13:32
PC Open Date & Time	09 SEP 2020 13:29
PC Close Date & Time	10 SEP 2020 11:59

US3792012
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:48:26

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	10 SEP 2020 14:29
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3792012
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:48:26

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

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	12 SEP 2020 17:40
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3792012
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:48:26

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 ●

US3792012
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:48:26

	Yes ◯
PC Time stamp	13 SEP 2020 17:49
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3792012
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:48:26

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	14 SEP 2020 17:34
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3792012

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:48:26

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	15 SEP 2020 18:02
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3792012

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) **01 Apr 2021 20:40:18**

Generated On: 10 Jun 2021 09:48:26

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

US3792012

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) **01 Apr 2021 20:40:18**

Generated On: 10 Jun 2021 09:48:26

Is the participant continuing to the next visit?   Yes ●

                                                                                      No ○

Continuing Flag   1

US3792012

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) **01 Apr 2021 20:40:18**

Generated On: 10 Jun 2021 09:48:26

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

Date of Contact or Contact Attempt *(dd MMM yyyy)*	24 SEP 2020
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ○

Comments

If Contact Not Made, please provide Comments _____

US3792012

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) **01 Apr 2021 20:40:18**

Generated On: 10 Jun 2021 09:48:26

Is the participant continuing to the next visit? Yes ⬤

No ◯

Continuing Flag 1

US3792012
Folder: Safety Call Day 50 (1)
Form: Safety Call
Data signed: (b) (4) **01 Apr 2021 20:40:18**
Generated On: 10 Jun 2021 09:48:26

| 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

If Contact Not Made, please provide Comments

US3792012

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) **01 Apr 2021 20:40:18**

Generated On: 10 Jun 2021 09:48:26

Is the participant continuing to the next visit?   Yes ●

                                                                                     No ○

Continuing Flag   1

US3792012

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) **01 Apr 2021 20:41:01**

Generated On: 10 Jun 2021 09:48:26

Was this visit performed?	Yes ●
	No ○
Visit date (dd MMM yyyy)	7 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●
Folder OID	VISIT3

FDA-CBER-2022-1614-3381062

US3792012

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) **01 Apr 2021 20:41:01**

Generated On: 10 Jun 2021 09:48:26

Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	7 OCT 2020
Time of assessment *(00:00-23:59)*	08:54 (24 HR)
Vital Signs Date and Time (derived)	7 OCT 2020 08:54
Temperature *(xxx.x)*	97.4 F
Route of measurement	Oral ●
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	68 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	143 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	91 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

FDA-CBER-2022-1614-3381063

US3792012

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) **01 Apr 2021 20:41:01**

Generated On: 10 Jun 2021 09:48:26

Was the physical examination performed?   Yes ⬤

                                                          No ◯

Date of examination *(dd MMM yyyy)*   7 OCT 2020

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

US3792012

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) **01 Apr 2021 20:41:01**

Generated On: 10 Jun 2021 09:48:26

Was the sample collected?	Yes ⬤
	No ◯
Collection date *(dd MMM yyyy)*	7 OCT 2020
Collection time *(00:00-23:59)*	09:01 (24 HR)
Collection date and time (derived)	7 OCT 2020 09:01

US3792012

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) **01 Apr 2021 20:41:01**

Generated On: 10 Jun 2021 09:48:26

Is the participant continuing to the next visit?   Yes ⬤

No ◯

Continuing Flag   1

US3792012
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26

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	12 OCT 2020 04:55:04
Patient Cloud Open Date & Time	12 OCT 2020 00:01
Patient Cloud Close Date & Time	16 OCT 2020 23:59

US3792012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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	21 OCT 2020 15:23:22
Patient Cloud Open Date & Time	19 OCT 2020 00:01
Patient Cloud Close Date & Time	23 OCT 2020 23:59

US3792012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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	26 OCT 2020 17:18:34
Patient Cloud Open Date & Time	26 OCT 2020 00:01
Patient Cloud Close Date & Time	30 OCT 2020 23:59

US3792012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤
	Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤
	Yes ◯
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 NOV 2020 12:35:54
Patient Cloud Open Date & Time	09 NOV 2020 00:01
Patient Cloud Close Date & Time	13 NOV 2020 23:59

US3792012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 NOV 2020 12:01:11
Patient Cloud Open Date & Time	16 NOV 2020 00:01
Patient Cloud Close Date & Time	20 NOV 2020 23:59

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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-2022-1614-3381072

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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	27 NOV 2020 05:43:44
Patient Cloud Open Date & Time	27 NOV 2020 00:01
Patient Cloud Close Date & Time	01 DEC 2020 23:59

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 DEC 2020 16:08:29
Patient Cloud Open Date & Time	04 DEC 2020 00:01
Patient Cloud Close Date & Time	08 DEC 2020 23:59

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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	13 DEC 2020 12:02:08
Patient Cloud Open Date & Time	11 DEC 2020 00:01
Patient Cloud Close Date & Time	15 DEC 2020 23:59

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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	22 DEC 2020 12:56:20
Patient Cloud Open Date & Time	18 DEC 2020 00:01
Patient Cloud Close Date & Time	22 DEC 2020 23:59

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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	27 DEC 2020 12:00:48
Patient Cloud Open Date & Time	25 DEC 2020 00:01
Patient Cloud Close Date & Time	29 DEC 2020 23:59

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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	03 JAN 2021 12:26:58
Patient Cloud Open Date & Time	01 JAN 2021 00:01
Patient Cloud Close Date & Time	05 JAN 2021 23:59

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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	08 JAN 2021 16:39:07
Patient Cloud Open Date & Time	08 JAN 2021 00:01
Patient Cloud Close Date & Time	12 JAN 2021 23:59

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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	15 JAN 2021 13:06:08
Patient Cloud Open Date & Time	15 JAN 2021 00:01
Patient Cloud Close Date & Time	19 JAN 2021 23:59

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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	22 JAN 2021 13:03:50
Patient Cloud Open Date & Time	22 JAN 2021 00:01
Patient Cloud Close Date & Time	26 JAN 2021 23:59

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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	29 JAN 2021 13:42:10
Patient Cloud Open Date & Time	29 JAN 2021 00:01
Patient Cloud Close Date & Time	02 FEB 2021 23:59

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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	07 FEB 2021 12:00:33
Patient Cloud Open Date & Time	05 FEB 2021 00:01
Patient Cloud Close Date & Time	09 FEB 2021 23:59

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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	14 FEB 2021 12:00:29
Patient Cloud Open Date & Time	12 FEB 2021 00:01
Patient Cloud Close Date & Time	16 FEB 2021 23:59

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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	19 FEB 2021 04:59:20
Patient Cloud Open Date & Time	19 FEB 2021 00:01
Patient Cloud Close Date & Time	23 FEB 2021 23:59

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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	26 FEB 2021 14:28:34
Patient Cloud Open Date & Time	26 FEB 2021 00:01
Patient Cloud Close Date & Time	02 MAR 2021 23:59

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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	07 MAR 2021 12:00:36
Patient Cloud Open Date & Time	05 MAR 2021 00:01
Patient Cloud Close Date & Time	09 MAR 2021 23:59

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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	12 MAR 2021 06:00:58
Patient Cloud Open Date & Time	12 MAR 2021 00:01
Patient Cloud Close Date & Time	16 MAR 2021 23:59

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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	19 MAR 2021 04:54:55
Patient Cloud Open Date & Time	19 MAR 2021 00:01
Patient Cloud Close Date & Time	23 MAR 2021 23:59

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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	26 MAR 2021 05:39:23
Patient Cloud Open Date & Time	26 MAR 2021 00:01
Patient Cloud Close Date & Time	30 MAR 2021 23:59

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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	02 APR 2021 07:22:02
Patient Cloud Open Date & Time	02 APR 2021 00:01
Patient Cloud Close Date & Time	06 APR 2021 23:59

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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	09 APR 2021 06:13:57
Patient Cloud Open Date & Time	09 APR 2021 00:01
Patient Cloud Close Date & Time	13 APR 2021 23:59

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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	16 APR 2021 05:11:12
Patient Cloud Open Date & Time	16 APR 2021 00:01
Patient Cloud Close Date & Time	20 APR 2021 23:59

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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 identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 APR 2021 06:05:04
Patient Cloud Open Date & Time	23 APR 2021 00:01
Patient Cloud Close Date & Time	27 APR 2021 23:59

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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 identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	30 APR 2021 06:58:55
Patient Cloud Open Date & Time	30 APR 2021 00:01
Patient Cloud Close Date & Time	04 MAY 2021 23:59

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

TIMEPOINT	**DAY 271**

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

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

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

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

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

TIMEPOINT	**DAY 278**

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

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

Fever (Temperature $\geq$ 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-2022-1614-3381099

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

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-2022-1614-3381101

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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

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

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

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

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26

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

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

TIMEPOINT   DAY 299

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

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

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-2022-1614-3381105

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

TIMEPOINT	**DAY 306**

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

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

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

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

FDA-CBER-2022-1614-3381107

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

TIMEPOINT	DAY 313
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

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

FDA-CBER-2022-1614-3381109

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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):

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-2022-1614-3381111

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26

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

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

TIMEPOINT	DAY 327

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

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

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

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

FDA-CBER-2022-1614-3381113

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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

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

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

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

FDA-CBER-2022-1614-3381115

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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):

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 ◯

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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 ≥ 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 ◯

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

TIMEPOINT	**DAY 355**

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

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

Fever (Temperature $\geq$ 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 ◯

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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):

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-2022-1614-3381123

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

TIMEPOINT	DAY 369
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⭕
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⭕ Yes ⭕

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

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

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

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

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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-2022-1614-3381127

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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):

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-2022-1614-3381129

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

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

TIMEPOINT	**DAY 390**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ◯
Yes ◯

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ◯
Yes ◯

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ◯

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

No ◯
Yes ◯

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ◯

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

No ◯
Yes ◯

FDA-CBER-2022-1614-3381131

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26

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

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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

FDA-CBER-2022-1614-3381133

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

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

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

FDA-CBER-2022-1614-3381135

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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):

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-2022-1614-3381137

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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 $\geq$ 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 ◯

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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 $\geq$ 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-2022-1614-3381141

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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):

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-2022-1614-3381143

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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 ≥ 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 ⭘

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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 $\geq$ 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-2022-1614-3381147

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

TIMEPOINT	**DAY 453**

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

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

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 ◯

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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):

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 ⃝

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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-2022-1614-3381153

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

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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 $\geq$ 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 ◯

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

TIMEPOINT   DAY 481

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

FDA-CBER-2022-1614-3381157

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26

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

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

TIMEPOINT	**DAY 488**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ◯
Yes ◯

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ◯
Yes ◯

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ◯

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

No ◯
Yes ◯

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ◯

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

No ◯
Yes ◯

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

TIMEPOINT DAY 495

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

FDA-CBER-2022-1614-3381161

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

TIMEPOINT DAY 502

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

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

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

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

FDA-CBER-2022-1614-3381163

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

TIMEPOINT	DAY 509

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

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

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

FDA-CBER-2022-1614-3381165

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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):

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 ◯

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

TIMEPOINT	DAY 523

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

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

Fever (Temperature $\geq$ 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 ⬭

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

TIMEPOINT	DAY 530

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

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

Fever (Temperature $\geq$ 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 ◯

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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 ◯

FDA-CBER-2022-1614-3381173

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

TIMEPOINT	**DAY 544**

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

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

Fever (Temperature $\geq$ 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	04 FEB 2022 00:01
Patient Cloud Close Date & Time	08 FEB 2022 23:59

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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 ◯

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26

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

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

TIMEPOINT	DAY 558
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

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

FDA-CBER-2022-1614-3381179

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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):

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-2022-1614-3381181

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

TIMEPOINT	DAY 572

| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No ◯ |
| | Yes ◯ |

| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No ◯ |
| | Yes ◯ |

| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately ◯ |

| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No ◯ |
| | Yes ◯ |

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

Fever (Temperature $\geq$ 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-2022-1614-3381183

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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-2022-1614-3381185

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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):

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 ◯

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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 $\geq$ 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	25 MAR 2022 00:01
Patient Cloud Close Date & Time	29 MAR 2022 23:59

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 $\geq$ 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-2022-1614-3381191

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

TIMEPOINT DAY 607

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

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

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

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

FDA-CBER-2022-1614-3381193

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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-2022-1614-3381195

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

TIMEPOINT	**DAY 621**

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

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

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

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

FDA-CBER-2022-1614-3381197

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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

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

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

FDA-CBER-2022-1614-3381199

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

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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):

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-2022-1614-3381201

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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 ◯

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

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

TIMEPOINT	DAY 649

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

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

Fever (Temperature $\geq$ 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 ⬭

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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 $\geq$ 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 ◯

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26

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

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

TIMEPOINT	**DAY 663**

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

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

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

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

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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-2022-1614-3381211

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

TIMEPOINT	**DAY 677**

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

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

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

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

FDA-CBER-2022-1614-3381213

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

TIMEPOINT   DAY 684

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

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

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

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

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

TIMEPOINT DAY 691

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

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

Fever (Temperature $\geq$ 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	01 JUL 2022 00:01
Patient Cloud Close Date & Time	05 JUL 2022 23:59

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

TIMEPOINT DAY 698

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

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

Fever (Temperature $\geq$ 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-2022-1614-3381219

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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 ◯

FDA-CBER-2022-1614-3381221

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

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

TIMEPOINT	DAY 712

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

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

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-2022-1614-3381223

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

TIMEPOINT DAY 719

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

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

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

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26

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

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

TIMEPOINT	**DAY 726**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

Fever (Temperature $\geq$ 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 ◯

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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):

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 ⚪

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26

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

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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 $\geq$ 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 ◯

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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 ⭘

FDA-CBER-2022-1614-3381233

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

TIMEPOINT	DAY 754

| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No ◯ |
| | Yes ◯ |

| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No ◯ |
| | Yes ◯ |

| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately ◯ |

| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No ◯ |
| | Yes ◯ |

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

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

| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately ◯ |

| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No ◯ |
| | Yes ◯ |

FDA-CBER-2022-1614-3381235

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

TIMEPOINT	**DAY 761**

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

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

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

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

FDA-CBER-2022-1614-3381237

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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):

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-2022-1614-3381239

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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 ◯

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

TIMEPOINT	**DAY 789**

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

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

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

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

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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 $\geq$ 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-2022-1614-3381247

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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

US3792012

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:48:26

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		28 FEB 2021 23:46:15

US3792012

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4)   **01 Apr 2021 20:40:18**

Generated On: 10 Jun 2021 09:48:26

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

| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 5 NOV 2020 |

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

Comments

If Contact Not Made, please provide Comments

US3792012

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) **01 Apr 2021 20:40:18**

Generated On: 10 Jun 2021 09:48:26

Is the participant continuing to the next visit?   Yes ●

                                                                                    No ○

Continuing Flag   1

US3792012

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4)   **01 Apr 2021 20:40:18**

Generated On: 10 Jun 2021 09:48:26

Was Contact Attempted?	Yes ●
	No ○
Date of Contact or Contact Attempt *(dd MMM yyyy)*	8 DEC 2020
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ○

Comments

If Contact Not Made, please provide Comments

US3792012

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) **01 Apr 2021 20:40:18**

Generated On: 10 Jun 2021 09:48:26

Is the participant continuing to the next visit?   Yes ●

                                                                                                         No ○

Continuing Flag   1

US3792012

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) **01 Apr 2021 20:40:18**

Generated On: 10 Jun 2021 09:48:26

Was Contact Attempted?	Yes ●
	No ○
Date of Contact or Contact Attempt *(dd MMM yyyy)*	6 JAN 2021
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ○

Comments

If Contact Not Made, please provide Comments

US3792012

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) **01 Apr 2021 20:40:18**

Generated On: 10 Jun 2021 09:48:26

Is the participant continuing to the next visit?   Yes ●

                                                                    No ○

Continuing Flag   1

US3792012

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) **01 Apr 2021 20:40:18**

Generated On: 10 Jun 2021 09:48:26

Was Contact Attempted?	Yes ●
	No ○
Date of Contact or Contact Attempt *(dd MMM yyyy)*	5 FEB 2021
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ○

Comments

If Contact Not Made, please provide Comments

US3792012

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) **01 Apr 2021 20:40:18**

Generated On: 10 Jun 2021 09:48:26

Is the participant continuing to the next visit?   Yes ⬤

                                                         No ◯

Continuing Flag   1

US3792012

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4)   **01 Apr 2021 20:41:01**

Generated On: 10 Jun 2021 09:48:26

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

US3792012

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) **08 Apr 2021 22:49:29**

Generated On: 10 Jun 2021 09:48:26

Were vital signs assessed?	Yes ●
	No ◯
Date of assessment *(dd MMM yyyy)*	24 MAR 2021
Time of assessment *(00:00-23:59)*	09:37 (24 HR)
Vital Signs Date and Time (derived)	24 MAR 2021 09:37
Temperature *(xxx.x)*	98.2 F
Route of measurement	Oral ●
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	78 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

FDA-CBER-2022-1614-3381259

US3792012

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4)   **01 Apr 2021 20:41:01**

Generated On: 10 Jun 2021 09:48:26

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.

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) **01 Apr 2021 20:41:01**

Generated On: 10 Jun 2021 09:48:26

| Was the sample collected? | Yes ● |
| | No ○ |

Collection date *(dd MMM yyyy)*	24 MAR 2021
Collection time *(00:00-23:59)*	09:45 (24 HR)
Collection date and time (derived)	24 MAR 2021 09:45

US3792012

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) **01 Apr 2021 20:41:01**

Generated On: 10 Jun 2021 09:48:26

Is the participant continuing to the next visit?   Yes ⬤

No ◯

Continuing Flag   1

US3792012

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) **08 Apr 2021 22:49:29**

Generated On: 10 Jun 2021 09:48:26

Was Contact Attempted?	Yes ⬤
	No ◯
Date of Contact or Contact Attempt *(dd MMM yyyy)*	7 APR 2021
Please select one status for the follow-up contact	Contact Made ⬤
	Contact Not Made ◯

Comments

If Contact Not Made, please provide Comments

US3792012

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) **08 Apr 2021 22:49:29**

Generated On: 10 Jun 2021 09:48:26

Is the participant continuing to the next visit?   Yes ●

                                                                          No ○

Continuing Flag   1

US3792012
Folder: Safety Call Day 269 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:48:26

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   _____

US3792012
Folder: Safety Call Day 269 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:48:26

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

Continuing Flag

US3792012
Folder: Covid-19 Assessment (1)
Form: COVID-19 Contact
Generated On: 10 Jun 2021 09:48:26

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 ⬭
	No ⬭

US3792012

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

Form: Visit Date

Data signed: (b) (4) **01 Apr 2021 20:40:18**

Generated On: 10 Jun 2021 09:48:26

Was this visit performed?	Yes ●
	No ○

Visit date (dd MMM yyyy)	6 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●

Folder OID	UNBLND_DECIDE

US3792012

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

Form: Unblinding

Data signed: (b) (4) **01 Apr 2021 20:40:18**

Generated On: 10 Jun 2021 09:48:26

Date of updated informed consent *(dd MMM yyyy)*	6 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)*	6 JAN 2021
Participant randomization assignment	mRNA-1273 ●
	Placebo ○
Actual Dose 1	mRNA-1273 ●
	Placebo ○
	Not Administered ○
Actual Dose 2	mRNA-1273 ●
	Placebo ○
	Not Administered ○
Will participant receive mRNA-1273?	Yes ○
	No ●
Placebo Only Flag	
Continuing with mRNA-1273	

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

Form: Immunogenicity Assessment

Data signed: (b) (4) **01 Apr 2021 20:40:18**

Generated On: 10 Jun 2021 09:48:26

Was the sample collected?	Yes ●
	No ○
Collection date *(dd MMM yyyy)*	6 JAN 2021
Collection time *(00:00-23:59)*	13:05 (24 HR)
Collection date and time (derived)	6 JAN 2021 13:05

US3792012

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) **01 Apr 2021 20:40:18**

Generated On: 10 Jun 2021 09:48:26

Was the sample collected?	Yes ●
	No ○
Collection date *(dd MMM yyyy)*	6 JAN 2021
Collection time *(00:00 - 23:59)*	13:09
Collection Date and Time (derived)	6 JAN 2021 13:09

US3792012

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) **01 Apr 2021 20:40:18**

Generated On: 10 Jun 2021 09:48:26

Did the participant experience any adverse events?   Yes ●

                                                                                                                  No ◯

If Yes, enter details on the Adverse Events form.

US3792012

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) **19 Apr 2021 16:11:05**

Generated On: 10 Jun 2021 09:48:26

AEID	
Adverse event	DIARRHEA
Was this a medically-attended AE?	Yes ⚪
	No ⚫
Was this a Solicited Adverse Reaction?	Yes ⚪
	No ⚫
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ⚪
	No ⚫
Start date *(dd MMM yyyy)*	21 SEP 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ⚪
	No ⚫
If not Ongoing, end date *(dd MMM yyyy)*	23 SEP 2020
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ⚫
	Grade 2/Moderate ⚪
	Grade 3/Severe ⚪
	Grade 4 ⚪
Is the adverse event serious?	Yes ⚪
	No ⚫
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ⚪
	No ⚪
	Unknown ⚪
Number of Days in ICU	

US3792012

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) **19 Apr 2021 16:11:05**

Generated On: 10 Jun 2021 09:48:26

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: PT FEELS LIKELY FOOD BORNE ILLNESS

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)	

US3792012

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) **19 Apr 2021 16:11:05**

Generated On: 10 Jun 2021 09:48:26

AEID	USA-US057-2021-MRNA-1273-P30 1000002
Adverse event	WORSENING OF CHRONIC BACK PAIN

Was this a medically-attended AE?　　Yes ●　No ○

Was this a Solicited Adverse Reaction?　　Yes ○　No ●

Is this event a confirmed diagnosis of Symptomatic Covid-19?　　Yes ○　No ●

Start date *(dd MMM yyyy)*	10 JAN 2021
Start time *(00:00-23:59)*	
AE start date and time (derived)	

Ongoing?　　Yes ○　No ●

If not Ongoing, end date *(dd MMM yyyy)*	19 FEB 2021
End time *(00:00-23:59)*	
AE End Date and Time (derived)	

Severity　　Grade 1/Mild ○　Grade 2/Moderate ○　Grade 3/Severe ●　Grade 4 ○

Is the adverse event serious?　　Yes ●　No ○

AE is serious due To (check all that apply)

Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date *(dd MMM yyyy)*	17 FEB 2021
Hospital Discharge Date *(dd MMM yyyy)*	19 FEB 2021

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

US3792012

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) **19 Apr 2021 16:11:05**

Generated On: 10 Jun 2021 09:48:26

	EXPERIENCED A WORSENING OF CHRONIC BACK PAIN IN JANUARY 2021. EVALUATION PERFORMED BY PHYSICIAN DETERMINED L4-L5 FUSION RECOMMENDED. SURGERY, L4-L5 FUSION PERFORMED ON 17FEB2021. RELEASED FROM HOSPITAL ON 19FEB2021.PATIENT INFORMS THEY ARE RECOVERED AND RELEASED FROM DR'S CARE .
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

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) **01 Apr 2021 20:40:18**

Generated On: 10 Jun 2021 09:48:26

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

No ○

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

Name of Medication	LEVOTHYROXINE SODIUM

Prophylaxis
- Yes ◯
- No ●

Indication	HYPOTHYROIDISM
Dose per administration	25

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

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration
- Oral ●
- Topical ◯
- Subcutaneous ◯
- Transdermal ◯
- Intraocular ◯

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 2015
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 ●

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) **01 Apr 2021 20:40:18**

Generated On: 10 Jun 2021 09:48:26

Name of Medication	PANTOPRAZOLE SODIUM

Prophylaxis	Yes	◯
	No	⬤

Indication	GASTROESOPHAGEAL REFLUX DISEASE

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)*	UN UNK 2017
Start date completely unknown	False
Ongoing?	Yes ⬤
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ⬤

FDA-CBER-2022-1614-3381283

Name of Medication	LISINOPRIL

Prophylaxis

Yes ◯

No ⬤

Indication	HYPERTENSION
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 ◯

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 2015
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 ⬤

FDA-CBER-2022-1614-3381285

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4)   **01 Apr 2021 20:40:18**

Generated On: 10 Jun 2021 09:48:26

Name of Medication	VALCYCLOVIR HCL

Prophylaxis

Yes ◯
No ●

Indication	HERPES SYMPLEX TYPE I
Dose per administration	500

Dose unit

mg ●
ug ◯
mL ◯
g ◯
IU ◯
tablet ◯
capsule ◯
puff ◯
Other ◯

If dose unit is Other, specify _____

Frequency

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

If frequency is Other, specify _____

Route of administration

Oral ●
Topical ◯
Subcutaneous ◯
Transdermal ◯
Intraocular ◯

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

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 2018
Start date completely unknown	False
Ongoing?	Yes ⬤
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ⬤

Name of Medication	PREVAGEN APOAEQUORIN TOTAL CARBOHYDRATE

Prophylaxis

Yes ◯
No ⬤

Indication	NUTRITIONAL SUPPLEMENT
Dose per administration	1

Dose unit

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

If dose unit is Other, specify

Frequency

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

If frequency is Other, specify

Route of administration

Oral ⬤
Topical ◯
Subcutaneous ◯
Transdermal ◯

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

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 2017
Start date completely unknown	False
Ongoing?	Yes ●
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ●
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ●

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) **01 Apr 2021 20:40:18**

Generated On: 10 Jun 2021 09:48:26

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

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

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 2017
Start date completely unknown	False
Ongoing?	Yes ●
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ●
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ●

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4)   **01 Apr 2021 20:40:18**

Generated On: 10 Jun 2021 09:48:26

Name of Medication	MULTIVITAMIN
Prophylaxis	Yes ⭕
	No ⬤
Indication	NUTRITIONAL SUPPLEMENT
Dose per administration	1

Dose unit

- mg ⭕
- ug ⭕
- mL ⭕
- g ⭕
- IU ⭕
- tablet ⬤
- capsule ⭕
- puff ⭕
- Other ⭕

If dose unit is Other, specify

Frequency

- once daily ⬤
- twice daily ⭕
- three times daily ⭕
- four times daily ⭕
- every other day ⭕
- every week ⭕
- every month ⭕
- as needed ⭕
- once ⭕
- unknown ⭕
- other ⭕

If frequency is Other, specify

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 2000
Start date completely unknown	False
Ongoing?	Yes ⬤
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ⬤

Name of Medication	VOLTAREN

Prophylaxis	Yes ◯
	No ⬤

Indication	LEFT HAND PAIN

Dose per administration	1

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

If dose unit is Other, specify	APPLICATION

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

If frequency is Other, specify	

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

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

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 2018
Start date completely unknown	False
Ongoing?	Yes ●
	No ○
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ○
	No ●
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ○
	803 ○
	804 ○

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) **01 Apr 2021 20:40:18**

Generated On: 10 Jun 2021 09:48:26

Name of Medication	FLU VACCINE
Prophylaxis	Yes ●
	No ○
Indication	FLU PROPHYLAXIS
Dose per administration	1
Dose unit	mg ○
	ug ○
	mL ○
	g ○
	IU ○
	tablet ○
	capsule ○
	puff ○
	Other ●
If dose unit is Other, specify	INJECTION
Frequency	once daily ○
	twice daily ○
	three times daily ○
	four times daily ○
	every other day ○
	every week ○
	every month ○
	as needed ○
	once ●
	unknown ○
	other ○
If frequency is Other, specify	
Route of administration	Oral ○
	Topical ○
	Subcutaneous ○
	Transdermal ○
	Intraocular ○

	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)*	25 SEP 2020
Start date completely unknown	False
Ongoing?	Yes ○
	No ●
If not Ongoing, End date *(dd MMM yyyy)*	25 SEP 2020
Was this medication taken for solicited event?	Yes ○
	No ●
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ○
	803 ○
	804 ○

US3792012

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) **01 Apr 2021 20:40:18**

Generated On: 10 Jun 2021 09:48:26

Were any concomitant procedures performed?   Yes ●

                                                              No ◯

If yes, please complete Concomitant Procedures form.

US3792012

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) **01 Apr 2021 20:40:18**

Generated On: 10 Jun 2021 09:48:26

Procedure/Surgery date (*dd MMM yyyy*)	Procedure/Surgery	Indication	If indication is Other, specify
17 FEB 2021	L4-L5 FUSION	Medical History	

US3792012
Folder: End of Study (1)
Form: Dosing Discontinuation
Generated On: 10 Jun 2021 09:48:26

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-US057-2021-MRNA-1273-P30 1000002
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	ABRAM
Investigator's Last Name	BURGHER
Site Address: Street	3900 EAST CAMELBACK ROAD
Site Address: City	PHOENIX
Site Address: State	
Site Address: Postal Code	85018
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3792012

Folder: SAE USA-US057-2021-MRNA-1273-P301000002

Form: Safety Report Form (1)

Data signed: (b) (4) **28 Apr 2021 05:39:29**

Generated On: 10 Jun 2021 09:48:26

SAEID	USA-US057-2021-MRNA-1273-P30 1000002
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	ABRAM
Investigator's Last Name	BURGHER
Site Address: Street	3900 EAST CAMELBACK ROAD
Site Address: City	PHOENIX
Site Address: State	
Site Address: Postal Code	85018
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	25/MAR/2021 13:23
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3792012

Folder: SAE USA-US057-2021-MRNA-1273-P301000002

Form: Safety Report Form (2)

Data signed: (b) (4) **28 Apr 2021 05:39:29**

Generated On: 10 Jun 2021 09:48:26

SAEID	USA-US057-2021-MRNA-1273-P30 1000002
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	ABRAM
Investigator's Last Name	BURGHER
Site Address: Street	3900 EAST CAMELBACK ROAD
Site Address: City	PHOENIX
Site Address: State	
Site Address: Postal Code	85018
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	05/APR/2021 10:47
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

US3792012

Folder: SAE USA-US057-2021-MRNA-1273-P301000002

Form: Safety Report Form (3)

Data signed: (b) (4) **28 Apr 2021 05:39:29**

Generated On: 10 Jun 2021 09:48:26

SAEID	USA-US057-2021-MRNA-1273-P30 1000002
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	ABRAM
Investigator's Last Name	BURGHER
Site Address: Street	3900 EAST CAMELBACK ROAD
Site Address: City	PHOENIX
Site Address: State	
Site Address: Postal Code	85018
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	12/APR/2021 11:15
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3792012

Folder: SAE USA-US057-2021-MRNA-1273-P301000002

Form: Safety Report Form (4)

Data signed: (b) (4) **28 Apr 2021 05:39:29**

Generated On: 10 Jun 2021 09:48:26

SAEID	USA-US057-2021-MRNA-1273-P30 1000002
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	ABRAM
Investigator's Last Name	BURGHER
Site Address: Street	3900 EAST CAMELBACK ROAD
Site Address: City	PHOENIX
Site Address: State	
Site Address: Postal Code	85018
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	19/APR/2021 12:37
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

US3792012 (Prod: Hope Research Institute LLC - Hunt - PPDS)

US3792012
Form: Participant Creation
Generated On: 10 Jun 2021 09:48:26
Participant ID

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:17:28
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
	(b) (4)	
User entered 'US3792012'	RWS_ENDPOINT ENDPOINT (b) (4)	12 Aug 2020 16:09:30

US3792012
Folder: Screening
Form: Visit Date
Generated On: 10 Jun 2021 09:48:26
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:29:13
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	12 Aug 2020 17:06:45

US3792012
Folder: Screening
Form: Visit Date
Generated On: 10 Jun 2021 09:48:26

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 20:29:16
User entered '12 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	12 Aug 2020 16:09:31

US3792012

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:48:26

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 10:15:25
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:29:16
User entered 'Clinic (Clinic)'	Norma Frederick (b) (4)	12 Aug 2020 17:06:45

US3792012
Folder: Screening
Form: Visit Date
Generated On: 10 Jun 2021 09:48:26
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User entered 'SCRN'	System	12 Aug 2020 17:06:45

US3792012

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:48:26

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:58:24
User entered (b) (6) 1948'	RWS_ENDPOINT ENDPOINT (b) (4)	12 Aug 2020 16:09:31

US3792012

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:48:26

Age

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 21:58:26
User entered '71'	Norma Frederick (b) (4) (b) (4)	12 Aug 2020 17:07:04

US3792012
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:48:26
Age Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User entered 'YEARS'	System	12 Aug 2020 17:07:04

US3792012
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:48:26
Age (Derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User entered '72'	System	12 Aug 2020 17:07:23

US3792012

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:48:26

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 21:58:28
User entered 'Male (M)'	Norma Frederick (b) (4) (b) (4)	12 Aug 2020 17:07:04

US3792012

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:48:26

Ethnicity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	18 Sep 2020 23:18:54
User closed query 'Source notes "Unknown". Please confirm. ' (Site from CRA).	(b) (4), (b) (6)	18 Sep 2020 23:18:51
Query 'Source notes "Unknown". Please confirm. ' answered with 'corrected' (Site from CRA).	Bettie Corcoran (b) (4) (b) (4)	16 Sep 2020 17:58:33
User entered 'Unknown (UNKNOWN)' reason for change: Data Entry Error	Bettie Corcoran (b) (4) (b) (4)	16 Sep 2020 17:58:14
DataPoint Un-verified.	(b) (4), (b) (6)	10 Sep 2020 21:58:45
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 21:58:42
User opened query 'Source notes "Unknown". Please confirm. ' (Site from CRA).	(b) (4), (b) (6)	10 Sep 2020 21:58:18
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Norma Frederick (b) (4) (b) (4)	12 Aug 2020 17:07:04

US3792012
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:48:26
White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 21:58:35
User entered '1'	Norma Frederick (b) (4)	12 Aug 2020 17:07:04
	(b) (4)	

US3792012
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:48:26
Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 21:58:42
User entered '0'	Norma Frederick (b) (4) (b) (4)	12 Aug 2020 17:07:04

US3792012
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:48:26
Asian

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 21:58:42
User entered '0'	Norma Frederick (b) (4) (b) (4)	12 Aug 2020 17:07:04

US3792012

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:48:26

American Indian or Alaska Native

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 21:58:42
User entered '0'	Norma Frederick (b) (4) (b) (4)	12 Aug 2020 17:07:04

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 21:58:42
User entered '0'	Norma Frederick (b) (4) (b) (4)	12 Aug 2020 17:07:04

US3792012

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:48:26

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 21:58:42
User entered '0'	Norma Frederick (b) (4)	12 Aug 2020 17:07:04
	(b) (4)	

US3792012
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:48:26
If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 21:58:42
User entered empty.	Norma Frederick (b) (4) (b) (4)	12 Aug 2020 17:07:04

US3792012
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:48:26
Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 21:58:42
User entered '0'	Norma Frederick (b) (4) (b) (4)	12 Aug 2020 17:07:04

US3792012
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:48:26
Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	10 Sep 2020 21:58:42
User entered '0'	Norma Frederick (b) (4) (b) (4)	12 Aug 2020 17:07:04

US3792012

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:48:26

Date of Informed Consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:30:21
User entered '12 Aug 2020'	Norma Frederick (b) (4) (b) (4)	12 Aug 2020 17:07:23

US3792012

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:48:26

Month and Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User entered 'Aug 2020'	System	12 Aug 2020 17:07:23

US3792012

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:48:26

Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User entered '2020'	System	12 Aug 2020 17:07:23

US3792012

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:48:26

Protocol Version

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:30:21
User entered 'Amendment 2 (2)'	Norma Frederick (b) (4) (b) (4)	12 Aug 2020 17:07:23

US3792012

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:48:26

Was participant enrolled in the study?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:30:21
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	12 Aug 2020 17:07:23

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:30:21
User entered empty.	Norma Frederick (b) (4) (b) (4)	12 Aug 2020 17:07:23

US3792012

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:48:26

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:30:21
User entered empty.	Norma Frederick (b) (4) (b) (4)	12 Aug 2020 17:07:23

US3792012
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 09:48:26

Was this participant screened previously?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:30:21
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	12 Aug 2020 17:07:23

US3792012

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:48:26

If Yes, previous participant number

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 20:30:21
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	12 Aug 2020 16:09:31

US3792012

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:48:26

Enrollment Trigger

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User entered '1'	System	12 Aug 2020 17:07:31

US3792012

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:48:26

Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:31:12
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	12 Aug 2020 17:07:31

US3792012

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 09:48:26

Were any significant conditions reported?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:34:10
User entered 'Yes (Y)'	Scarlett Hammett (b) (4) (b) (4)	14 Aug 2020 22:58:06

US3792012

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:48:26

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:35:55
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 20:24:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 20:24:30
Data point term sent to Coder	System	20 Aug 2020 20:23:02
User entered 'hypothyriodism'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:22:03

US3792012

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:48:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:35:55
User entered 'un UNK 2015'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:22:03

US3792012

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:48:26

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:35:55
User entered '0'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:22:03

US3792012

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:48:26

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:35:55
User entered 'Yes (Y)'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:22:03

US3792012

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:48:26

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:35:55
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:22:03

US3792012

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:48:26

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:35:55
User entered '0'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:22:03

US3792012

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:48:26

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User entered 'Jan 2015'	System	20 Aug 2020 20:22:03

US3792012

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:48:26

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User entered '2015'	System	20 Aug 2020 20:22:03

US3792012

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:48:26

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User entered empty.	System	20 Aug 2020 20:22:03

US3792012

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:48:26

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User entered empty.	System	20 Aug 2020 20:22:03

US3792012

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:48:26

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:35:55
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 20:24:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 20:24:32
Data point term sent to Coder	System	20 Aug 2020 20:23:02
User entered 'hypertension'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:22:26

US3792012

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:48:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:35:55
User entered 'un UNK 2015'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:22:26

US3792012

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:48:26

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:35:55
User entered '0'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:22:26

US3792012

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:48:26

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:35:55
User entered 'Yes (Y)'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:22:26

US3792012

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:48:26

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:35:55
User entered empty.	Scarlett Hammett (b) (4)	20 Aug 2020 20:22:26
	(b) (4)	

US3792012

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:48:26

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:35:55
User entered '0'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:22:26

US3792012

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:48:26

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User entered 'Jan 2015'	System	20 Aug 2020 20:22:26

US3792012

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:48:26

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User entered '2015'	System	20 Aug 2020 20:22:26

US3792012

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:48:26

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User entered empty.	System	20 Aug 2020 20:22:26

US3792012

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:48:26

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User entered empty.	System	20 Aug 2020 20:22:26

US3792012

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:48:26

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:35:55
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: Gastroesophageal reflux disease - version MedDRA\\23.0.	Coder Import ^{(b) (4)} (b) (4)	20 Aug 2020 20:24:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import ^{(b) (4)} (b) (4)	20 Aug 2020 20:24:33
Data point term sent to Coder	System	20 Aug 2020 20:23:06
User entered 'gastroesophageal reflux disease'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:23:01

US3792012

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:48:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:35:55
User entered 'un UNK 2017'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:23:01

US3792012

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:48:26

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:35:55
User entered '0'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:23:01

US3792012

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:48:26

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:35:55
User entered 'Yes (Y)'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:23:01

US3792012

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:48:26

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:35:55
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:23:01

US3792012

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:48:26

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:35:55
User entered '0'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:23:01

US3792012

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:48:26

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User entered 'Jan 2017'	System	20 Aug 2020 20:23:01

US3792012

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:48:26

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User entered '2017'	System	20 Aug 2020 20:23:01

US3792012

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:48:26

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User entered empty.	System	20 Aug 2020 20:23:01

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User entered empty.	System	20 Aug 2020 20:23:01

US3792012

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:48:26

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:35:55
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Herpes viral infections, PT: Herpes simplex, LLT: Herpes simplex type I - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 23:50:25
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 23:50:25
Data point term sent to Coder	System	20 Aug 2020 20:24:07
User entered 'herpes symplex type I'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:23:41

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	18 Sep 2020 23:19:21
User closed query 'Source states as start date 1997. Please confirm. ' (Site from CRA).	(b) (4), (b) (6)	18 Sep 2020 23:19:19
Query 'Source states as start date 1997. Please confirm. ' answered with 'corrected' (Site from CRA).	Bettie Corcoran (b) (4) (b) (4)	16 Sep 2020 17:59:31
User entered 'UN UNK 1997' reason for change: Data Entry Error	Bettie Corcoran (b) (4) (b) (4)	16 Sep 2020 17:59:25
DataPoint Un-verified.	(b) (4), (b) (6)	11 Sep 2020 20:36:35
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:35:55
User opened query 'Source states as start date 1997. Please confirm. ' (Site from CRA).	(b) (4), (b) (6)	11 Sep 2020 20:35:15
User entered 'un UNK 2017'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:23:41

US3792012

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:48:26

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:35:55
User entered '0'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:23:41

US3792012

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:48:26

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:35:55
User entered 'Yes (Y)'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:23:41

US3792012

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:48:26

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:35:55
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:23:41

US3792012

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:48:26

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:35:55
User entered '0'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:23:41

US3792012

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:48:26

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User entered 'Jan 1997'	System	16 Sep 2020 17:59:25
User entered 'Jan 2017'	System	20 Aug 2020 20:23:41

US3792012

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:48:26

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User entered '1997'	System	16 Sep 2020 17:59:25
User entered '2017'	System	20 Aug 2020 20:23:41

US3792012
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 09:48:26
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User entered empty.	System	20 Aug 2020 20:23:41

US3792012
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 09:48:26
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User entered empty.	System	20 Aug 2020 20:23:41

US3792012

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:48:26

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:35:55
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Cutaneous neoplasms benign, HLT: Skin neoplasms benign, PT: Skin papilloma, LLT: Wart - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Aug 2020 07:03:15
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Aug 2020 07:03:15
Data point term sent to Coder	System	20 Aug 2020 20:25:12
User entered 'wart left arm'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:24:50

US3792012

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:48:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:35:55
User entered 'UN UNK 2010' reason for change: Data Entry Error	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:25:55
User entered 'un Jul 2020'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:24:50

US3792012

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:48:26

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:35:55
User entered '0'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:24:50

US3792012

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:48:26

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:35:55
User entered 'No (N)'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:24:50

US3792012

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:48:26

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:35:55
User entered 'un Jul 2020'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:24:50

US3792012
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 09:48:26
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:35:55
User entered '0'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:24:50

US3792012

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:48:26

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User entered 'Jan 2010'	System	20 Aug 2020 20:25:55
User entered 'Jul 2020'	System	20 Aug 2020 20:24:50

US3792012

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:48:26

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User entered '2010'	System	20 Aug 2020 20:25:55
User entered '2020'	System	20 Aug 2020 20:24:50

US3792012

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:48:26

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User entered 'Jul 2020'	System	20 Aug 2020 20:24:50

US3792012

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:48:26

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User entered '2020'	System	20 Aug 2020 20:24:50

US3792012

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:48:26

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:35:55
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Cutaneous neoplasms benign, HLT: Skin neoplasms benign, PT: Skin papilloma, LLT: Wart - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Aug 2020 07:04:09
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Aug 2020 07:04:09
Data point term sent to Coder	System	20 Aug 2020 20:26:15
User entered 'wart right arm'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:25:29

US3792012

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:48:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:35:55
User entered 'un UNK 2010'	Scarlett Hammett (b) (4)	20 Aug 2020 20:25:29

US3792012

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:48:26

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:35:55
User entered '0'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:25:29

US3792012

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:48:26

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:35:55
User entered 'No (N)'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:25:29

US3792012

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:48:26

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:35:55
User entered 'un Jul 2020'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:25:29

US3792012

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:48:26

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:35:55
User entered '0'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:25:29

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:48:26

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User entered 'Jan 2010'	System	20 Aug 2020 20:25:29

US3792012

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:48:26

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User entered '2010'	System	20 Aug 2020 20:25:29

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:48:26

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User entered 'Jul 2020'	System	20 Aug 2020 20:25:29

US3792012

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:48:26

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User entered '2020'	System	20 Aug 2020 20:25:29

US3792012

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:48:26

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:35:55
User coded data point as SOC: Ear and labyrinth disorders, HLGT: Inner ear and VIIIth cranial nerve disorders, HLT: Inner ear signs and symptoms, PT: Tinnitus, LLT: Tinnitus - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Aug 2020 07:36:09
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Aug 2020 07:36:09
Data point term sent to Coder	System	20 Aug 2020 20:27:21
User entered 'tinnitis bilateral ears'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:26:31

US3792012

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:48:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 20:35:55
User entered 'un UNK 2005'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:26:31

US3792012

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:48:26

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:35:55
User entered '0'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:26:31

US3792012

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:48:26

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:35:55
User entered 'Yes (Y)'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:26:31

US3792012

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:48:26

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:35:55
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:26:31

US3792012

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:48:26

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:35:55
User entered '0'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:26:31

US3792012
Folder: Screening
Form: Medical History (7)
Generated On: 10 Jun 2021 09:48:26
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User entered 'Jan 2005'	System	20 Aug 2020 20:26:31

US3792012

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:48:26

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User entered '2005'	System	20 Aug 2020 20:26:31

US3792012
Folder: Screening
Form: Medical History (7)
Generated On: 10 Jun 2021 09:48:26
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User entered empty.	System	20 Aug 2020 20:26:31

US3792012
Folder: Screening
Form: Medical History (7)
Generated On: 10 Jun 2021 09:48:26
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User entered empty.	System	20 Aug 2020 20:26:31

US3792012

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:48:26

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:35:55
User coded data point as SOC: Renal and urinary disorders, HLGT: Urinary tract signs and symptoms, HLT: Urinary tract signs and symptoms NEC, PT: Polyuria, LLT: Polyuria - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 20:28:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 20:28:27
Data point term sent to Coder	System	20 Aug 2020 20:27:22
User entered 'polyuria'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:26:53

US3792012

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:48:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:35:55
User entered 'un UNK 2015'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:26:53

US3792012

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:48:26

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:35:55
User entered '0'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:26:53

US3792012

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:48:26

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:35:55
User entered 'Yes (Y)'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:26:53

US3792012

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:48:26

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:35:55
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:26:53

US3792012

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:48:26

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:35:55
User entered '0'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:26:53

US3792012
Folder: Screening
Form: Medical History (8)
Generated On: 10 Jun 2021 09:48:26
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User entered 'Jan 2015'	System	20 Aug 2020 20:26:53

US3792012
Folder: Screening
Form: Medical History (8)
Generated On: 10 Jun 2021 09:48:26
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User entered '2015'	System	20 Aug 2020 20:26:53

US3792012

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:48:26

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User entered empty.	System	20 Aug 2020 20:26:53

US3792012

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:48:26

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User entered empty.	System	20 Aug 2020 20:26:53

US3792012

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:48:26

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:35:55
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Prostatic disorders (excl infections and inflammations), HLT: Prostatic neoplasms and hypertrophy, PT: Benign prostatic hyperplasia, LLT: Benign prostatic hyperplasia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 20:29:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 20:29:30
Data point term sent to Coder	System	20 Aug 2020 20:28:25
User entered 'benign prostatic hyperplasia'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:27:28

US3792012

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:48:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:35:55
User entered 'un UNK 2015'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:27:28

US3792012

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:48:26

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:35:55
User entered '0'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:27:28

US3792012

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:48:26

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:35:55
User entered 'Yes (Y)'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:27:28

US3792012

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:48:26

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 20:35:55
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:27:28

US3792012

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:48:26

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:35:55
User entered '0'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:27:28

US3792012
Folder: Screening
Form: Medical History (9)
Generated On: 10 Jun 2021 09:48:26

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User entered 'Jan 2015'	System	20 Aug 2020 20:27:28

US3792012

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:48:26

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User entered '2015'	System	20 Aug 2020 20:27:28

US3792012

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:48:26

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User entered empty.	System	20 Aug 2020 20:27:28

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User entered empty.	System	20 Aug 2020 20:27:28

US3792012

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:48:26

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:35:55
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Hand osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 20:29:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 20:29:30
Data point term sent to Coder	System	20 Aug 2020 20:28:25
User entered 'left hand osteoarthritis'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:28:04

US3792012

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:48:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:35:55
User entered 'un UNK 2018'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:28:04

US3792012

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:48:26

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:35:55
User entered '0'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:28:04

US3792012

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:48:26

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:35:55
User entered 'Yes (Y)'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:28:04

US3792012

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:48:26

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:35:55
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:28:04

US3792012

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:48:26

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:35:55
User entered '0'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:28:04

US3792012
Folder: Screening
Form: Medical History (10)
Generated On: 10 Jun 2021 09:48:26
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User entered 'Jan 2018'	System	20 Aug 2020 20:28:04

US3792012
Folder: Screening
Form: Medical History (10)
Generated On: 10 Jun 2021 09:48:26
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User entered '2018'	System	20 Aug 2020 20:28:04

US3792012
Folder: Screening
Form: Medical History (10)
Generated On: 10 Jun 2021 09:48:26
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User entered empty.	System	20 Aug 2020 20:28:04

US3792012
Folder: Screening
Form: Medical History (10)
Generated On: 10 Jun 2021 09:48:26
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User entered empty.	System	20 Aug 2020 20:28:04

US3792012

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:48:26

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:35:55
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Pain in extremity, LLT: Hand pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Aug 2020 06:41:18
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Aug 2020 06:41:18
Data point term sent to Coder	System	20 Aug 2020 20:30:29
User entered 'left hand pain'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:30:09

US3792012

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:48:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:35:55
User entered 'un UNK 2018'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:30:09

US3792012

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:48:26

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:35:55
User entered '0'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:30:09

US3792012

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:48:26

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:35:55
User entered 'Yes (Y)'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:30:09

US3792012

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:48:26

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:35:55
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:30:09

US3792012

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:48:26

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:35:55
User entered '0'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:30:09

FDA-CBER-2022-1614-3381445

US3792012
Folder: Screening
Form: Medical History (11)
Generated On: 10 Jun 2021 09:48:26
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User entered 'Jan 2018'	System	20 Aug 2020 20:30:09

US3792012

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:48:26

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User entered '2018'	System	20 Aug 2020 20:30:09

US3792012

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:48:26

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User entered empty.	System	20 Aug 2020 20:30:09

US3792012

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:48:26

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User entered empty.	System	20 Aug 2020 20:30:09

US3792012

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:48:26

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:09:43
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Chronic back pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Mar 2021 21:20:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Mar 2021 21:20:52
Data point term sent to Coder	System	24 Mar 2021 21:20:07
User entered 'Chronic Back pain'	(b) (4), (b) (6)	24 Mar 2021 21:19:44

US3792012

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:48:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:09:36
User closed query 'Source does not indicate start date, if ongoing/stop date. Please update source.' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 18:09:14
Query 'Source does not indicate start date, if ongoing/stop date. Please update source.' answered with 'Source updated' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 23:00:16
User opened query 'Source does not indicate start date, if ongoing/stop date. Please update source.' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 18:10:30
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 18:09:45
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:09:43
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
User entered 'un UNK 2011'	(b) (4), (b) (6)	24 Mar 2021 21:19:44

US3792012

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:48:26

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:09:43
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
User entered '0'	(b) (4), (b) (6)	24 Mar 2021 21:19:44

US3792012

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:48:26

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:09:43
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:19:44

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:48:26

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:09:43
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:19:44

US3792012

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:48:26

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:09:43
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
User entered '0'	(b) (4), (b) (6)	24 Mar 2021 21:19:44

US3792012
Folder: Screening
Form: Medical History (13)
Generated On: 10 Jun 2021 09:48:26
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User entered 'Jan 2011'	System	24 Mar 2021 21:19:44

US3792012

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:48:26

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User entered '2011'	System	24 Mar 2021 21:19:44

US3792012

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:48:26

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User entered empty.	System	24 Mar 2021 21:19:44

US3792012

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:48:26

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User entered empty.	System	24 Mar 2021 21:19:44

US3792012

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:26

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:38:33
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	12 Aug 2020 18:31:12

FDA-CBER-2022-1614-3381460

US3792012

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:26

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:38:33
User entered '12 Aug 2020'	Norma Frederick (b) (4) (b) (4)	12 Aug 2020 18:31:12

US3792012

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:26

Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:38:33
User entered '09:49'	Norma Frederick (b) (4) (b) (4)	12 Aug 2020 18:31:12

US3792012
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:48:26
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User entered '12 Aug 2020 09:49'	System	12 Aug 2020 18:31:12

US3792012
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:48:26

Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:38:33
User entered '67' in	Norma Frederick (b) (4) (b) (4)	12 Aug 2020 18:31:12
DataPoint set to visible.	System	12 Aug 2020 17:07:31

US3792012

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:26

Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:38:33
User entered '212' lb	Norma Frederick (b) (4)	12 Aug 2020 18:31:12
DataPoint set to visible.	System	12 Aug 2020 17:07:31

US3792012
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:48:26
BMI *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
Amendment Manager: User entered '33.27332'	System	16 Sep 2020 23:53:38
User entered '33.3'	System	12 Aug 2020 18:31:12
DataPoint set to visible.	System	12 Aug 2020 17:07:31

US3792012
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:48:26
BMI units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User entered 'kg/m2'	System	12 Aug 2020 18:31:12
DataPoint set to visible.	System	12 Aug 2020 17:07:31

US3792012
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:48:26
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:38:33
User entered missing code ND - Not Done; reason for change Data Entry Error	Norma Frederick (b) (4) (b) (4)	31 Aug 2020 19:37:53
User entered '97.5' F	Norma Frederick (b) (4) (b) (4)	12 Aug 2020 18:31:12

US3792012

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:26

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:38:33
User entered empty; reason for change Data Entry Error	Norma Frederick (b) (4) (b) (4)	31 Aug 2020 19:37:53
User entered 'Oral (Oral)'	Norma Frederick (b) (4) (b) (4)	12 Aug 2020 18:31:12

US3792012
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:48:26
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:38:33
User entered empty.	Norma Frederick (b) (4) (b) (4)	12 Aug 2020 18:31:12

US3792012
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:48:26
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:38:33
User entered missing code ND - Not Done; reason for change Data Entry Error	Norma Frederick (b) (4) (b) (4)	31 Aug 2020 19:37:53
User entered '73'	Norma Frederick (b) (4) (b) (4)	12 Aug 2020 18:31:12

US3792012
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:48:26
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User entered 'bpm'	System	12 Aug 2020 18:31:12

US3792012
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:48:26

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:38:33
User entered missing code ND - Not Done; reason for change Data Entry Error	Norma Frederick (b) (4) (b) (4)	31 Aug 2020 19:37:53
User entered '20'	Norma Frederick (b) (4) (b) (4)	12 Aug 2020 18:31:12

FDA-CBER-2022-1614-3381473

US3792012
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:48:26
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User entered 'breaths/min'	System	12 Aug 2020 18:31:12

US3792012

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:26

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:38:33
User entered missing code ND - Not Done; reason for change Data Entry Error	Norma Frederick (b) (4) (b) (4)	31 Aug 2020 19:37:53
User entered '111'	Norma Frederick (b) (4) (b) (4)	12 Aug 2020 18:31:12

US3792012
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:48:26
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User entered 'mmHg'	System	12 Aug 2020 18:31:12

US3792012
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:48:26
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:38:33
User entered missing code ND - Not Done; reason for change Data Entry Error	Norma Frederick (b) (4) (b) (4)	31 Aug 2020 19:37:53
User entered '77'	Norma Frederick (b) (4) (b) (4)	12 Aug 2020 18:31:12

US3792012
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:48:26
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User entered 'mmHg'	System	12 Aug 2020 18:31:12

US3792012
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:48:26
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25

US3792012
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:48:26
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25

US3792012

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:48:26

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:39:59
User entered 'Yes (Y)'	Scarlett Hammett (b) (4) (b) (4)	14 Aug 2020 22:57:53

US3792012

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:48:26

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:39:59
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	11 Sep 2020 15:47:33
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	09 Sep 2020 17:24:34
User entered '12 Aug 2020'	Scarlett Hammett (b) (4) (b) (4)	14 Aug 2020 22:57:53

US3792012

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:48:26

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 10:15:25
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 20:41:46
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	12 Aug 2020 17:08:54

US3792012

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:48:26

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 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:41:46
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	12 Aug 2020 17:08:54

US3792012

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:48:26

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 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:41:46
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	12 Aug 2020 17:08:54

US3792012

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:48:26

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 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:41:46
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	12 Aug 2020 17:08:54

US3792012

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:48:26

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 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:41:46
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	12 Aug 2020 17:08:54

US3792012

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:48:26

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 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:41:46
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	12 Aug 2020 17:08:54

US3792012

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:48:26

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 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:41:46
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	12 Aug 2020 17:08:54

US3792012

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:48:26

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 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:41:46
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	12 Aug 2020 17:08:54

US3792012

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:48:26

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 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:41:46
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	12 Aug 2020 17:08:54

US3792012

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:48:26

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 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:41:46
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	12 Aug 2020 17:08:54

US3792012

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:48:26

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 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:41:46
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	12 Aug 2020 17:08:54

US3792012
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:48:26
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:41:46
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	12 Aug 2020 17:08:54

US3792012

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:48:26

Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:41:46
User entered 'volunteers at the (b) (6) hospital'	Norma Frederick (b) (4) (b) (4)	12 Aug 2020 17:08:54

US3792012

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:48:26

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
User entered '0'	Norma Frederick (b) (4) (b) (4)	12 Aug 2020 17:08:54

US3792012

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:48:26

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 20:41:46
User entered '0'	Norma Frederick (b) (4) (b) (4)	12 Aug 2020 17:08:54

US3792012

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:48:26

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 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:41:46
User entered '0'	Norma Frederick (b) (4) (b) (4)	12 Aug 2020 17:08:54

US3792012

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:48:26

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 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:41:46
User entered '0'	Norma Frederick (b) (4) (b) (4)	12 Aug 2020 17:08:54

US3792012

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:48:26

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 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:41:46
User entered '1'	Norma Frederick (b) (4) (b) (4)	12 Aug 2020 17:08:54

US3792012

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:48:26

Resides in a single family home (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 20:41:46
User entered '0'	Norma Frederick (b) (4) (b) (4)	12 Aug 2020 17:08:54

US3792012

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:48:26

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
User entered '0'	Norma Frederick (b) (4) (b) (4)	12 Aug 2020 17:08:54

US3792012
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:48:26
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:41:46
User entered empty.	Norma Frederick (b) (4) (b) (4)	12 Aug 2020 17:08:54

US3792012
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 10 Jun 2021 09:48:26
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 13:55:57
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:32:29
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:42:21
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	12 Aug 2020 17:09:40

US3792012
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 10 Jun 2021 09:48:26

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 13:55:57
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:32:29
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:42:21
User entered '12 Aug 2020'	Norma Frederick (b) (4) (b) (4)	12 Aug 2020 17:09:40

US3792012
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 10 Jun 2021 09:48:26

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 10:15:25
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 13:55:57
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:32:29
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:42:21
User entered 'Clinic (Clinic)'	Norma Frederick (b) (4) (b) (4)	12 Aug 2020 17:09:40

US3792012

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:48:26

Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 13:55:57
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:32:29
User entered 'VISIT1'	System	12 Aug 2020 17:09:40

US3792012

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:48:26

What was the date of randomization? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 13:55:59
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:32:29
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 20:45:12
User entered '12 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	12 Aug 2020 17:09:28

US3792012

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:48:26

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 13:55:59
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:32:29
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 20:45:12
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 03:53:21
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:53:21
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	12 Aug 2020 17:09:28
User entered '185515' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	12 Aug 2020 17:09:28

US3792012

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:48:26

In what Cohort was the participant enrolled?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 13:55:59
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:32:29
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 20:45:12
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	12 Aug 2020 17:09:28

US3792012

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:48:26

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 Apr 2021 10:15:25
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 13:55:59
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:32:29
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:45:12
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	12 Aug 2020 17:09:53

US3792012

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:48:26

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 Apr 2021 10:15:25
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 13:55:59
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:32:29
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:45:12
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	12 Aug 2020 17:09:53

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 13:55:59
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:32:29
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:45:12
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	12 Aug 2020 17:09:53

US3792012

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:48:26

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 13:55:59
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:32:29
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:45:12
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	12 Aug 2020 17:09:53

US3792012

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:48:26

Liver Disease

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 13:55:59
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:32:29
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:45:12
User entered 'No (N)'	Norma Frederick (b) (4) (b) (4)	12 Aug 2020 17:09:53

US3792012

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:48:26

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:50:15
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 13:55:59
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:32:29
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
User entered 'No (N)'	Scarlett Hammett (b) (4) (b) (4)	26 Sep 2020 00:27:46
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:18:40
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 06:47:14

US3792012
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 09:48:26
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 13:56:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:32:29
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:47:30
User entered missing code ND - Not Done; reason for change Data Entry Error	Scarlett Hammett (b) (4) (b) (4)	14 Aug 2020 23:03:50
User entered '67' in reason for change: Data Entry Error	Scarlett Hammett (b) (4) (b) (4)	14 Aug 2020 23:01:52
User entered missing code ND - Not Done.	Norma Frederick (b) (4) (b) (4)	13 Aug 2020 22:16:06

US3792012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:48:26

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 13:56:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:32:29
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:47:30
User entered missing code ND - Not Done; reason for change Data Entry Error	Scarlett Hammett (b) (4) (b) (4)	14 Aug 2020 23:03:50
User entered '212' lb reason for change: Data Entry Error	Scarlett Hammett (b) (4) (b) (4)	14 Aug 2020 23:01:52
User entered missing code ND - Not Done.	Norma Frederick (b) (4) (b) (4)	13 Aug 2020 22:16:06

US3792012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:48:26

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 13:56:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:32:29
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:47:30
User entered missing code ND - Not Done; reason for change Data Entry Error	Scarlett Hammett (b) (4) (b) (4)	14 Aug 2020 23:03:50
User entered '67' in reason for change: Data Entry Error	Scarlett Hammett (b) (4) (b) (4)	14 Aug 2020 23:01:52
User entered missing code ND - Not Done.	Norma Frederick (b) (4) (b) (4)	13 Aug 2020 22:16:06

US3792012
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 09:48:26
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 13:56:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:32:29
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:47:30
User entered missing code ND - Not Done; reason for change Data Entry Error	Scarlett Hammett (b) (4) (b) (4)	14 Aug 2020 23:03:50
User entered '212' lb reason for change: Data Entry Error	Scarlett Hammett (b) (4) (b) (4)	14 Aug 2020 23:01:52
User entered missing code ND - Not Done.	Norma Frederick (b) (4) (b) (4)	13 Aug 2020 22:16:06

US3792012
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:48:26
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 13:56:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:32:29
User accepted default value 'Pre-Dose (PREDOSE)'	Norma Frederick (b) (4) (b) (4)	13 Aug 2020 22:16:06

US3792012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:26

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 13:56:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:32:29
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 20:47:30
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Aug 2020 23:01:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Aug 2020 23:01:08
User entered 'Yes (Y)' reason for change: Data Entry Error	Scarlett Hammett (b) (4) (b) (4)	14 Aug 2020 23:01:08
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Aug 2020 22:16:06
User entered empty.	Norma Frederick (b) (4) (b) (4)	13 Aug 2020 22:16:06

US3792012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:26

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 13:56:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:32:29
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:47:30
User entered '12 Aug 2020' reason for change: Data Entry Error	Scarlett Hammett (b) (4) (b) (4)	14 Aug 2020 23:01:08
User entered empty.	Norma Frederick (b) (4) (b) (4)	13 Aug 2020 22:16:06

US3792012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:26

Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 13:56:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:32:29
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:47:30
User entered '09:49' reason for change: Data Entry Error	Scarlett Hammett (b) (4) (b) (4)	14 Aug 2020 23:01:08
User entered empty.	Norma Frederick (b) (4) (b) (4)	13 Aug 2020 22:16:06

US3792012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:26

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 13:56:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:32:29
User entered '12 Aug 2020 09:49'	System	14 Aug 2020 23:01:08
User entered empty.	System	13 Aug 2020 22:16:06

US3792012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:26

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 13:56:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:32:29
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:47:30
User entered '97.5' F reason for change: Data Entry Error	Scarlett Hammett (b) (4) (b) (4)	14 Aug 2020 23:01:08
User entered empty.	Norma Frederick (b) (4) (b) (4)	13 Aug 2020 22:16:06

US3792012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:26

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 13:56:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:32:29
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:47:30
User entered 'Oral (Oral)' reason for change: Data Entry Error	Scarlett Hammett (b) (4) (b) (4)	14 Aug 2020 23:01:08
User entered empty.	Norma Frederick (b) (4) (b) (4)	13 Aug 2020 22:16:06

US3792012
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:48:26
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 13:56:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:32:29
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:47:30
User entered empty.	Norma Frederick (b) (4) (b) (4)	13 Aug 2020 22:16:06

US3792012
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:48:26
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 13:56:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:32:29
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:47:30
User entered '73' reason for change: Data Entry Error	Scarlett Hammett (b) (4) (b) (4)	14 Aug 2020 23:01:08
User entered empty.	Norma Frederick (b) (4) (b) (4)	13 Aug 2020 22:16:06

US3792012
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:48:26
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 13:56:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:32:29
User entered 'bpm'	System	14 Aug 2020 23:01:08
User entered empty.	System	13 Aug 2020 22:16:06

US3792012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:26

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 13:56:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:32:29
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:47:30
User entered '20' reason for change: Data Entry Error	Scarlett Hammett (b) (4) (b) (4)	14 Aug 2020 23:01:08
User entered empty.	Norma Frederick (b) (4) (b) (4)	13 Aug 2020 22:16:06

US3792012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:26

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 13:56:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:32:29
User entered 'breaths/min'	System	14 Aug 2020 23:01:08
User entered empty.	System	13 Aug 2020 22:16:06

US3792012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:26

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 13:56:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:32:29
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:47:30
User entered '111' reason for change: Data Entry Error	Scarlett Hammett (b) (4) (b) (4)	14 Aug 2020 23:01:08
User entered empty.	Norma Frederick (b) (4) (b) (4)	13 Aug 2020 22:16:06

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 13:56:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:32:29
User entered 'mmHg'	System	14 Aug 2020 23:01:08
User entered empty.	System	13 Aug 2020 22:16:06

FDA-CBER-2022-1614-3381534

US3792012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:26

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 13:56:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:32:29
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:47:30
User entered '77' reason for change: Data Entry Error	Scarlett Hammett (b) (4) (b) (4)	14 Aug 2020 23:01:08
User entered empty.	Norma Frederick (b) (4) (b) (4)	13 Aug 2020 22:16:06

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 13:56:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:32:29
User entered 'mmHg'	System	14 Aug 2020 23:01:08
User entered empty.	System	13 Aug 2020 22:16:06

FDA-CBER-2022-1614-3381536

US3792012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:48:26

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 13:56:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:32:29
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:47:30
User entered missing code ND - Not Done; reason for change Data Entry Error	Scarlett Hammett (b) (4) (b) (4)	14 Aug 2020 23:03:50
User entered '67' in reason for change: Data Entry Error	Scarlett Hammett (b) (4) (b) (4)	14 Aug 2020 23:01:52
User entered missing code ND - Not Done.	Norma Frederick (b) (4) (b) (4)	13 Aug 2020 22:16:06

US3792012
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 09:48:26
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 13:56:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:32:29
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:47:30
User entered missing code ND - Not Done; reason for change Data Entry Error	Scarlett Hammett (b) (4) (b) (4)	14 Aug 2020 23:03:50
User entered '212' lb reason for change: Data Entry Error	Scarlett Hammett (b) (4) (b) (4)	14 Aug 2020 23:01:52
User entered missing code ND - Not Done.	Norma Frederick (b) (4) (b) (4)	13 Aug 2020 22:16:06

US3792012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:26

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 13:56:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:32:29
User accepted default value 'Post-Dose (POSTDOSE)'	Norma Frederick (b) (4) (b) (4)	13 Aug 2020 22:16:06

US3792012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:26

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 13:56:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:32:29
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 20:47:30
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Aug 2020 23:03:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Aug 2020 23:03:06
User entered 'Yes (Y)' reason for change: Data Entry Error	Scarlett Hammett (b) (4) (b) (4)	14 Aug 2020 23:03:06
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Aug 2020 22:16:06
User entered empty.	Norma Frederick (b) (4) (b) (4)	13 Aug 2020 22:16:06

US3792012
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:48:26
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 13:56:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:32:29
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:47:30
User entered '12 Aug 2020' reason for change: Data Entry Error	Scarlett Hammett (b) (4) (b) (4)	14 Aug 2020 23:03:06
User entered empty.	Norma Frederick (b) (4) (b) (4)	13 Aug 2020 22:16:06

US3792012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:26

Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 13:56:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:32:29
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:47:30
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	16 Aug 2020 11:40:10
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'time correct as entered' (Site from System).	Scarlett Hammett (b) (4) (b) (4)	14 Aug 2020 23:04:05
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	System	14 Aug 2020 23:03:06
User entered '11:25' reason for change: Data Entry Error	Scarlett Hammett (b) (4) (b) (4)	14 Aug 2020 23:03:06
User entered empty.	Norma Frederick (b) (4) (b) (4)	13 Aug 2020 22:16:06

US3792012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:26

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 13:56:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:32:29
User entered '12 Aug 2020 11:25'	System	14 Aug 2020 23:03:06
User entered empty.	System	13 Aug 2020 22:16:06

US3792012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:26

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 13:56:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:32:29
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:47:30
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	14 Aug 2020 23:04:14
User entered '97.7' F reason for change: Data Entry Error	Scarlett Hammett (b) (4) (b) (4)	14 Aug 2020 23:04:14
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	14 Aug 2020 23:03:06
User entered '97.7' (non-conformant).	Scarlett Hammett (b) (4) (b) (4)	14 Aug 2020 23:03:06
User entered empty.	Norma Frederick (b) (4) (b) (4)	13 Aug 2020 22:16:06

US3792012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:26

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 13:56:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:32:29
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:47:30
User entered 'Oral (Oral)' reason for change: Data Entry Error	Scarlett Hammett (b) (4) (b) (4)	14 Aug 2020 23:03:06
User entered empty.	Norma Frederick (b) (4) (b) (4)	13 Aug 2020 22:16:06

US3792012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:26

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 13:56:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:32:29
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:47:30
User entered empty.	Norma Frederick (b) (4) (b) (4)	13 Aug 2020 22:16:06

US3792012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:26

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 13:56:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:32:29
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:47:30
User entered '72' reason for change: Data Entry Error	Scarlett Hammett (b) (4) (b) (4)	14 Aug 2020 23:03:06
User entered empty.	Norma Frederick (b) (4) (b) (4)	13 Aug 2020 22:16:06

US3792012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:26

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 13:56:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:32:29
User entered 'bpm'	System	14 Aug 2020 23:03:06
User entered empty.	System	13 Aug 2020 22:16:06

US3792012
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:48:26
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 13:56:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:32:29
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:47:30
User entered '20' reason for change: Data Entry Error	Scarlett Hammett (b) (4) (b) (4)	14 Aug 2020 23:03:06
User entered empty.	Norma Frederick (b) (4) (b) (4)	13 Aug 2020 22:16:06

US3792012
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:48:26
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 13:56:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:32:29
User entered 'breaths/min'	System	14 Aug 2020 23:03:06
User entered empty.	System	13 Aug 2020 22:16:06

US3792012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:26

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 13:56:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:32:29
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:47:30
User entered '125' reason for change: Data Entry Error	Scarlett Hammett (b) (4) (b) (4)	14 Aug 2020 23:03:06
User entered empty.	Norma Frederick (b) (4) (b) (4)	13 Aug 2020 22:16:06

US3792012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:26

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 13:56:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:32:29
User entered 'mmHg'	System	14 Aug 2020 23:03:06
User entered empty.	System	13 Aug 2020 22:16:06

US3792012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:26

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 13:56:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:32:29
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:47:30
User entered '83' reason for change: Data Entry Error	Scarlett Hammett (b) (4) (b) (4)	14 Aug 2020 23:03:06
User entered empty.	Norma Frederick (b) (4) (b) (4)	13 Aug 2020 22:16:06

US3792012

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:26

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 13:56:03
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:32:29
User entered 'mmHg'	System	14 Aug 2020 23:03:06
User entered empty.	System	13 Aug 2020 22:16:06

US3792012
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 10 Jun 2021 09:48:26
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 13:56:06
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:32:29
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:49:23
User entered 'No (N)' reason for change: Data Entry Error	Norma Frederick (b) (4) (b) (4)	31 Aug 2020 22:51:23
User entered 'Yes (Y)'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:30:56

US3792012

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:48:26

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 13:56:06
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:32:29
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:49:23
User entered empty; reason for change Data Entry Error	Norma Frederick (b) (4) (b) (4)	31 Aug 2020 22:51:23
User entered '12 Aug 2020'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:30:56

US3792012
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:48:26
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 13:56:08
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:32:29
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:50:23
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	12 Aug 2020 17:58:39

US3792012

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:48:26

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 13:56:08
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:32:29
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:50:23
User entered empty.	Norma Frederick (b) (4) (b) (4)	12 Aug 2020 17:58:39

US3792012

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:48:26

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 10:15:25
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 13:56:08
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:32:29
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:50:23
User entered empty.	Norma Frederick (b) (4) (b) (4)	12 Aug 2020 17:58:39

US3792012
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:48:26
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 13:56:08
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:32:29
User entered 'MRNA-1273 OR PLACEBO'	System	12 Aug 2020 17:58:39

What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 13:56:08
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:32:29
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:50:23
User entered '12 Aug 2020'	Norma Frederick (b) (4) (b) (4)	12 Aug 2020 17:58:39

US3792012

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:48:26

What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 13:56:08
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:32:29
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:50:23
User entered '10:43'	Norma Frederick (b) (4) (b) (4)	12 Aug 2020 17:58:39

US3792012

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:48:26

Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 13:56:08
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:32:29
User entered '12 Aug 2020 10:43'	System	12 Aug 2020 17:58:39

US3792012

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:48:26

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 13:56:08
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:32:29
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 20:50:23
User entered 'Left Arm (LEFT ARM)'	Norma Frederick (b) (4) (b) (4)	12 Aug 2020 17:58:39

US3792012
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:48:26

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 13:56:08
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:32:29
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:50:23
User entered 'ONCE'	System	12 Aug 2020 17:58:39

US3792012

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:48:26

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 13:56:08
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:32:29
User entered 'INTRAMUSCULAR'	System	12 Aug 2020 17:58:39

US3792012

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:48:26

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 13:56:13
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:32:29
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:51:30
User entered 'Yes (Y)'	Scarlett Hammett (b) (4) (b) (4)	10 Sep 2020 03:39:07

US3792012

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:48:26

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 13:56:13
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:32:29
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:51:30
User entered '12 Aug 2020'	Scarlett Hammett (b) (4) (b) (4)	10 Sep 2020 03:39:07

US3792012

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:48:26

Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 13:56:13
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:32:29
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:51:30
User entered '09:58'	Scarlett Hammett (b) (4) (b) (4)	10 Sep 2020 03:39:07

US3792012

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:48:26

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 13:56:13
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:32:29
User entered '12 Aug 2020 09:58'	System	10 Sep 2020 03:39:07

US3792012

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:48:26

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 13:56:16
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:32:29
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:51:59
User entered '12 Aug 2020'	Scarlett Hammett (b) (4) (b) (4)	10 Sep 2020 03:39:25

US3792012

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:48:26

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 13:56:16
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:32:29
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Scarlett Hammett (b) (4) (b) (4)	10 Sep 2020 03:39:25

US3792012

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:48:26

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 13:56:16
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:32:29
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:51:59
User entered 'Yes (Y)'	Scarlett Hammett (b) (4) (b) (4)	10 Sep 2020 03:39:25

US3792012

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:48:26

Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 13:56:16
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:32:29
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 20:51:59
User entered '10:00'	Scarlett Hammett (b) (4) (b) (4)	10 Sep 2020 03:39:25

US3792012

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:48:26

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 13:56:16
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:32:29
User entered '12 Aug 2020 10:00'	System	10 Sep 2020 03:39:25

US3792012

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:48:26

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 13:56:16
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:32:29
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Scarlett Hammett (b) (4) (b) (4)	10 Sep 2020 03:39:25

US3792012

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:48:26

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 13:56:16
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:32:29
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 20:51:59
User entered 'No (N)'	Scarlett Hammett (b) (4) (b) (4)	10 Sep 2020 03:39:25

US3792012

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:48:26

Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 13:56:16
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:32:29
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:51:59
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	10 Sep 2020 03:39:25

US3792012

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:48:26

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 13:56:16
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:32:29
User entered empty.	System	10 Sep 2020 03:39:25

US3792012
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 10 Jun 2021 09:48:26

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 13:56:19
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:32:29
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 20:52:08
User entered 'Yes (Y)'	Scarlett Hammett (b) (4)	20 Aug 2020 20:46:16

US3792012
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 10 Jun 2021 09:48:26
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:15:25
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 13:56:19
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:32:29
User entered '1'	System	20 Aug 2020 20:46:16

US3792012
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
Data entry locked.	System	12 Aug 2020 17:58:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Aug 2020 17:58:39

US3792012
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:48:26
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-12T11:26:03', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'a5f665dd-fe82-40d6-b4b7-61960698c0aa'	System	12 Aug 2020 18:27:07
User entered 'Yes (Y)'	System	12 Aug 2020 18:27:07

US3792012
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:48:26

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-12T11:26:33', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'a5f665dd-fe82-40d6-b4b7-61960698c0aa'	System	12 Aug 2020 18:27:07
User entered '97.7'	System	12 Aug 2020 18:27:07

US3792012
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:48:26

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-12T11:26:50', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'a5f665dd-fe82-40d6-b4b7-61960698c0aa'	System	12 Aug 2020 18:27:07
User entered 'No (N)'	System	12 Aug 2020 18:27:07

US3792012
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:48:26
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-12T11:27:05', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'a5f665dd-fe82-40d6-b4b7-61960698c0aa'	System	12 Aug 2020 18:27:07
User entered '12 Aug 2020 11:27'	System	12 Aug 2020 18:27:07

US3792012
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:48:26

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
User entered '12 Aug 2020 11:03'	System	12 Aug 2020 17:58:39

US3792012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:48:26

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
User entered '12 Aug 2020 13:33'	System	12 Aug 2020 17:58:39

US3792012
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
Data entry locked.	System	12 Aug 2020 17:58:39
User entered 'Day 1, after vaccination (at home)'	System	12 Aug 2020 17:58:39

US3792012
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:48:26
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-12T15:40:52', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '0f04a723-14ab-4dbb-a211-4bc9f6f7d402'	System	12 Aug 2020 22:41:26
User entered 'Yes (Y)'	System	12 Aug 2020 22:41:26

US3792012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:48:26

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-12T15:41:06', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '0f04a723-14ab-4dbb-a211-4bc9f6f7d402'	System	12 Aug 2020 22:41:26
User entered '97.1'	System	12 Aug 2020 22:41:26

FDA-CBER-2022-1614-3381591

US3792012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:48:26

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-12T15:41:12', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '0f04a723-14ab-4dbb-a211-4bc9f6f7d402'	System	12 Aug 2020 22:41:26
User entered 'No (N)'	System	12 Aug 2020 22:41:26

US3792012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:48:26

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-12T15:41:23', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '0f04a723-14ab-4dbb-a211-4bc9f6f7d402'	System	12 Aug 2020 22:41:26
User entered '12 Aug 2020 15:41'	System	12 Aug 2020 22:41:26

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
User entered '12 Aug 2020 14:28'	System	12 Aug 2020 17:58:39

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
User entered '13 Aug 2020 11:59'	System	12 Aug 2020 17:58:39

FDA-CBER-2022-1614-3381595

US3792012
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
Data entry locked.	System	12 Aug 2020 17:58:39
User entered 'Day 2'	System	12 Aug 2020 17:58:39

US3792012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:48:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-13T12:21:47', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '0614dea3-6818-47f0-85ee-65e881e72647'	System	13 Aug 2020 19:22:12
User entered 'Yes (Y)'	System	13 Aug 2020 19:22:12

US3792012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:48:26

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-13T12:21:55', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '0614dea3-6818-47f0-85ee-65e881e72647'	System	13 Aug 2020 19:22:12
User entered '97.6'	System	13 Aug 2020 19:22:12

US3792012
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:48:26

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-13T12:22:00', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '0614dea3-6818-47f0-85ee-65e881e72647'	System	13 Aug 2020 19:22:12
User entered 'No (N)'	System	13 Aug 2020 19:22:12

US3792012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:48:26

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-13T12:22:10', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '0614dea3-6818-47f0-85ee-65e881e72647'	System	13 Aug 2020 19:22:12
User entered '13 Aug 2020 12:22'	System	13 Aug 2020 19:22:12

US3792012
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:48:26
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
User entered '13 Aug 2020 12:00'	System	12 Aug 2020 17:58:39

US3792012
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:48:26
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
User entered '14 Aug 2020 11:59'	System	12 Aug 2020 17:58:39

Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
Data entry locked.	System	12 Aug 2020 17:58:39
User entered 'Day 3'	System	12 Aug 2020 17:58:39

US3792012
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:48:26
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-14T12:01:03', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'ca9d76c0-cb3a-4554-a497-4ea32c58ab1b'	System	14 Aug 2020 19:01:36
User entered 'Yes (Y)'	System	14 Aug 2020 19:01:36

US3792012
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:48:26

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-14T12:01:11', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'ca9d76c0-cb3a-4554-a497-4ea32c58ab1b'	System	14 Aug 2020 19:01:36
User entered '97.4'	System	14 Aug 2020 19:01:36

US3792012
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:48:26

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-14T12:01:16', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'ca9d76c0-cb3a-4554-a497-4ea32c58ab1b'	System	14 Aug 2020 19:01:36
User entered 'No (N)'	System	14 Aug 2020 19:01:36

US3792012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:48:26

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-14T12:01:26', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'ca9d76c0-cb3a-4554-a497-4ea32c58ab1b'	System	14 Aug 2020 19:01:36
User entered '14 Aug 2020 12:01'	System	14 Aug 2020 19:01:36

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
User entered '14 Aug 2020 12:00'	System	12 Aug 2020 17:58:39

US3792012
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:48:26
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
User entered '15 Aug 2020 11:59'	System	12 Aug 2020 17:58:39

US3792012
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
Data entry locked.	System	12 Aug 2020 17:58:39
User entered 'Day 4'	System	12 Aug 2020 17:58:39

US3792012
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:48:26
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-15T12:02:13', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '7cfe3d99-6e80-46ef-a4cd-f65b5f6b9339'	System	15 Aug 2020 19:02:42
User entered 'Yes (Y)'	System	15 Aug 2020 19:02:42

FDA-CBER-2022-1614-3381611

US3792012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:48:26

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-15T12:02:26', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '7cfe3d99-6e80-46ef-a4cd-f65b5f6b9339'	System	15 Aug 2020 19:02:42
User entered '99.1'	System	15 Aug 2020 19:02:42

US3792012
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:48:26

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-15T12:02:31', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '7cfe3d99-6e80-46ef-a4cd-f65b5f6b9339'	System	15 Aug 2020 19:02:42
User entered 'No (N)'	System	15 Aug 2020 19:02:42

FDA-CBER-2022-1614-3381613

US3792012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:48:26

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-15T12:02:37', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '7cfe3d99-6e80-46ef-a4cd-f65b5f6b9339'	System	15 Aug 2020 19:02:42
User entered '15 Aug 2020 12:02'	System	15 Aug 2020 19:02:42

US3792012
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:48:26

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
User entered '15 Aug 2020 12:00'	System	12 Aug 2020 17:58:39

US3792012
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:48:26
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
User entered '16 Aug 2020 11:59'	System	12 Aug 2020 17:58:39

US3792012
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
Data entry locked.	System	12 Aug 2020 17:58:39
User entered 'Day 5'	System	12 Aug 2020 17:58:39

US3792012
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:48:26
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-16T12:00:57', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '1dfbc20e-40c0-4785-9112-7da121993c70'	System	16 Aug 2020 19:01:16
User entered 'Yes (Y)'	System	16 Aug 2020 19:01:16

US3792012
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:48:26

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-16T12:01:03', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '1dfbc20e-40c0-4785-9112-7da121993c70'	System	16 Aug 2020 19:01:16
User entered '97.2'	System	16 Aug 2020 19:01:16

US3792012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:48:26

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-16T12:01:07', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '1dfbc20e-40c0-4785-9112-7da121993c70'	System	16 Aug 2020 19:01:16
User entered 'No (N)'	System	16 Aug 2020 19:01:16

US3792012
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:48:26
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-16T12:01:14', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '1dfbc20e-40c0-4785-9112-7da121993c70'	System	16 Aug 2020 19:01:16
User entered '16 Aug 2020 12:01'	System	16 Aug 2020 19:01:16

US3792012
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:48:26
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
User entered '16 Aug 2020 12:00'	System	12 Aug 2020 17:58:39

US3792012
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:48:26
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
User entered '17 Aug 2020 11:59'	System	12 Aug 2020 17:58:39

US3792012
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
Data entry locked.	System	12 Aug 2020 17:58:39
User entered 'Day 6'	System	12 Aug 2020 17:58:39

FDA-CBER-2022-1614-3381624

US3792012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:48:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-17T12:05:41', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'a663f8b4-62b3-4ec1-9908-cb275396f0aa'	System	17 Aug 2020 19:06:01
User entered 'Yes (Y)'	System	17 Aug 2020 19:06:01

US3792012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:48:26

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-17T12:05:49', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'a663f8b4-62b3-4ec1-9908-cb275396f0aa'	System	17 Aug 2020 19:06:01
User entered '97.4'	System	17 Aug 2020 19:06:01

US3792012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:48:26

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-17T12:05:54', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'a663f8b4-62b3-4ec1-9908-cb275396f0aa'	System	17 Aug 2020 19:06:01
User entered 'No (N)'	System	17 Aug 2020 19:06:01

FDA-CBER-2022-1614-3381627

US3792012
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:48:26
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-17T12:06:00', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'a663f8b4-62b3-4ec1-9908-cb275396f0aa'	System	17 Aug 2020 19:06:01
User entered '17 Aug 2020 12:06'	System	17 Aug 2020 19:06:01

US3792012
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:48:26
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
User entered '17 Aug 2020 12:00'	System	12 Aug 2020 17:58:39

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
User entered '18 Aug 2020 11:59'	System	12 Aug 2020 17:58:39

FDA-CBER-2022-1614-3381630

US3792012
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
Data entry locked.	System	12 Aug 2020 17:58:39
User entered 'Day 7'	System	12 Aug 2020 17:58:39

US3792012
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:48:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-18T13:16:52', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '5a716642-d328-4eac-920b-5154e0243b5c'	System	18 Aug 2020 20:17:10
User entered 'Yes (Y)'	System	18 Aug 2020 20:17:10

US3792012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:48:26

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-18T13:16:58', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '5a716642-d328-4eac-920b-5154e0243b5c'	System	18 Aug 2020 20:17:10
User entered '97.6'	System	18 Aug 2020 20:17:10

US3792012

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:48:26

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-18T13:17:01', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '5a716642-d328-4eac-920b-5154e0243b5c'	System	18 Aug 2020 20:17:10
User entered 'No (N)'	System	18 Aug 2020 20:17:10

US3792012
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:48:26
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-18T13:17:07', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '5a716642-d328-4eac-920b-5154e0243b5c'	System	18 Aug 2020 20:17:10
User entered '18 Aug 2020 13:17'	System	18 Aug 2020 20:17:10

US3792012
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:48:26
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
User entered '18 Aug 2020 12:00'	System	12 Aug 2020 17:58:39

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
User entered '19 Aug 2020 11:59'	System	12 Aug 2020 17:58:39

US3792012
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
Data entry locked.	System	12 Aug 2020 17:58:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Aug 2020 17:58:39

US3792012
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:48:26

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-12T11:27:37', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '6be7b05f-04b4-40ab-a1c6-cdbf77abfb49'	System	12 Aug 2020 18:28:30
User entered 'None (1)'	System	12 Aug 2020 18:28:30

US3792012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:48:26

Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-12T11:27:45', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '6be7b05f-04b4-40ab-a1c6-cdbf77abfb49'	System	12 Aug 2020 18:28:30
User entered 'No (N)'	System	12 Aug 2020 18:28:30

US3792012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:48:26

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-12T11:27:55', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '6be7b05f-04b4-40ab-a1c6-cdbf77abfb49'	System	12 Aug 2020 18:28:30
User entered 'No (N)'	System	12 Aug 2020 18:28:30

FDA-CBER-2022-1614-3381641

US3792012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:48:26

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-12T11:28:13', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '6be7b05f-04b4-40ab-a1c6-cdbf77abfb49'	System	12 Aug 2020 18:28:30
User entered 'None (1)'	System	12 Aug 2020 18:28:30

US3792012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:48:26

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-12T11:28:24', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '6be7b05f-04b4-40ab-a1c6-cdbf77abfb49'	System	12 Aug 2020 18:28:30
User entered '12 Aug 2020 11:28'	System	12 Aug 2020 18:28:30

US3792012
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:48:26

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
User entered '12 Aug 2020 11:03'	System	12 Aug 2020 17:58:39

US3792012
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:48:26
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
User entered '12 Aug 2020 13:33'	System	12 Aug 2020 17:58:39

US3792012
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
Data entry locked.	System	12 Aug 2020 17:58:39
User entered 'Day 1, after vaccination (at home)'	System	12 Aug 2020 17:58:39

US3792012
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:48:26
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-12T15:41:49', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'd976e34a-4669-42c1-afea-f3e2efc49d52'	System	12 Aug 2020 22:46:06
User entered 'Does not interfere with activity (2)'	System	12 Aug 2020 22:46:06

US3792012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:48:26

Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-12T15:42:24', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'd976e34a-4669-42c1-afea-f3e2efc49d52'	System	12 Aug 2020 22:46:06
User entered 'Yes (Y)'	System	12 Aug 2020 22:46:06

US3792012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:48:26

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-12T15:44:43', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'd976e34a-4669-42c1-afea-f3e2efc49d52'	System	12 Aug 2020 22:46:06
User entered '5'	System	12 Aug 2020 22:46:06

US3792012
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:48:26
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-12T15:44:55', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'd976e34a-4669-42c1-afea-f3e2efc49d52'	System	12 Aug 2020 22:46:06
User entered 'Yes (Y)'	System	12 Aug 2020 22:46:06

US3792012
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:48:26
Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-12T15:45:28', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'd976e34a-4669-42c1-afea-f3e2efc49d52'	System	12 Aug 2020 22:46:06
User entered '5'	System	12 Aug 2020 22:46:06

FDA-CBER-2022-1614-3381651

US3792012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:48:26

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-12T15:45:36', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'd976e34a-4669-42c1-afea-f3e2efc49d52'	System	12 Aug 2020 22:46:06
User entered 'Does not interfere with activity (2)'	System	12 Aug 2020 22:46:06

US3792012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:48:26

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-12T15:46:01', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'd976e34a-4669-42c1-afea-f3e2efc49d52'	System	12 Aug 2020 22:46:06
User entered '12 Aug 2020 15:46'	System	12 Aug 2020 22:46:06

US3792012
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:48:26
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
User entered '12 Aug 2020 14:28'	System	12 Aug 2020 17:58:39

US3792012
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:48:26
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
User entered '13 Aug 2020 11:59'	System	12 Aug 2020 17:58:39

US3792012
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
Data entry locked.	System	12 Aug 2020 17:58:39
User entered 'Day 2'	System	12 Aug 2020 17:58:39

US3792012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:48:26

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-13T12:22:23', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'c39b0a86-9232-43b3-a049-ff9f891c7cb6'	System	13 Aug 2020 19:23:20
User entered 'Does not interfere with activity (2)'	System	13 Aug 2020 19:23:20

US3792012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:48:26

Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-13T12:22:32', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'c39b0a86-9232-43b3-a049-ff9f891c7cb6'	System	13 Aug 2020 19:23:20
User entered 'No (N)'	System	13 Aug 2020 19:23:20

FDA-CBER-2022-1614-3381658

US3792012
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:48:26
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-13T12:22:36', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'c39b0a86-9232-43b3-a049-ff9f891c7cb6'	System	13 Aug 2020 19:23:20
User entered 'Yes (Y)'	System	13 Aug 2020 19:23:20

US3792012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:48:26

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-13T12:22:53', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'c39b0a86-9232-43b3-a049-ff9f891c7cb6'	System	13 Aug 2020 19:23:20
User entered '2'	System	13 Aug 2020 19:23:20

US3792012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:48:26

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-13T12:22:58', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'c39b0a86-9232-43b3-a049-ff9f891c7cb6'	System	13 Aug 2020 19:23:20
User entered 'Does not interfere with activity (2)'	System	13 Aug 2020 19:23:20

US3792012
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:48:26
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-13T12:23:19', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'c39b0a86-9232-43b3-a049-ff9f891c7cb6'	System	13 Aug 2020 19:23:20
User entered '13 Aug 2020 12:23'	System	13 Aug 2020 19:23:20

US3792012
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:48:26
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
User entered '13 Aug 2020 12:00'	System	12 Aug 2020 17:58:39

US3792012
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:48:26
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
User entered '14 Aug 2020 11:59'	System	12 Aug 2020 17:58:39

US3792012
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
Data entry locked.	System	12 Aug 2020 17:58:39
User entered 'Day 3'	System	12 Aug 2020 17:58:39

US3792012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:48:26

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-14T12:01:37', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '6836368c-8f91-4d0c-acfe-8259589fd623'	System	14 Aug 2020 19:02:18
User entered 'Does not interfere with activity (2)'	System	14 Aug 2020 19:02:18

US3792012
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:48:26
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-14T12:01:40', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '6836368c-8f91-4d0c-acfe-8259589fd623'	System	14 Aug 2020 19:02:18
User entered 'No (N)'	System	14 Aug 2020 19:02:18

US3792012
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:48:26
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-14T12:01:50', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '6836368c-8f91-4d0c-acfe-8259589fd623'	System	14 Aug 2020 19:02:18
User entered 'Yes (Y)'	System	14 Aug 2020 19:02:18

US3792012
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:48:26
Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-14T12:02:00', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '6836368c-8f91-4d0c-acfe-8259589fd623'	System	14 Aug 2020 19:02:18
User entered '5'	System	14 Aug 2020 19:02:18

FDA-CBER-2022-1614-3381669

US3792012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:48:26

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-14T12:02:07', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '6836368c-8f91-4d0c-acfe-8259589fd623'	System	14 Aug 2020 19:02:18
User entered 'Does not interfere with activity (2)'	System	14 Aug 2020 19:02:18

US3792012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:48:26

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-14T12:02:17', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '6836368c-8f91-4d0c-acfe-8259589fd623'	System	14 Aug 2020 19:02:18
User entered '14 Aug 2020 12:02'	System	14 Aug 2020 19:02:18

US3792012
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:48:26

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
User entered '14 Aug 2020 12:00'	System	12 Aug 2020 17:58:39

US3792012
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:48:26
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
User entered '15 Aug 2020 11:59'	System	12 Aug 2020 17:58:39

US3792012
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
Data entry locked.	System	12 Aug 2020 17:58:39
User entered 'Day 4'	System	12 Aug 2020 17:58:39

US3792012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:48:26

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-15T12:02:50', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '541f0446-fba3-481d-8eb3-cdb8a8a1e08a'	System	15 Aug 2020 19:03:08
User entered 'None (1)'	System	15 Aug 2020 19:03:08

US3792012
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:48:26
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-15T12:02:54', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '541f0446-fba3-481d-8eb3-cdb8a8a1e08a'	System	15 Aug 2020 19:03:08
User entered 'No (N)'	System	15 Aug 2020 19:03:08

US3792012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:48:26

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-15T12:02:58', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '541f0446-fba3-481d-8eb3-cdb8a8a1e08a'	System	15 Aug 2020 19:03:08
User entered 'No (N)'	System	15 Aug 2020 19:03:08

FDA-CBER-2022-1614-3381677

US3792012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:48:26

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-15T12:03:02', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '541f0446-fba3-481d-8eb3-cdb8a8a1e08a'	System	15 Aug 2020 19:03:08
User entered 'None (1)'	System	15 Aug 2020 19:03:08

US3792012
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:48:26
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-15T12:03:06', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '541f0446-fba3-481d-8eb3-cdb8a8a1e08a'	System	15 Aug 2020 19:03:08
User entered '15 Aug 2020 12:03'	System	15 Aug 2020 19:03:08

US3792012
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:48:26
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
User entered '15 Aug 2020 12:00'	System	12 Aug 2020 17:58:39

US3792012
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:48:26
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
User entered '16 Aug 2020 11:59'	System	12 Aug 2020 17:58:39

US3792012
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
Data entry locked.	System	12 Aug 2020 17:58:39
User entered 'Day 5'	System	12 Aug 2020 17:58:39

US3792012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:48:26

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-16T12:01:22', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '8223b4c5-63ac-46e8-b1c9-3681fffd52d0'	System	16 Aug 2020 19:01:57
User entered 'None (1)'	System	16 Aug 2020 19:01:57

US3792012
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:48:26
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-16T12:01:26', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '8223b4c5-63ac-46e8-b1c9-3681fffd52d0'	System	16 Aug 2020 19:01:57
User entered 'No (N)'	System	16 Aug 2020 19:01:57

US3792012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:48:26

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-16T12:01:30', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '8223b4c5-63ac-46e8-b1c9-3681fffd52d0'	System	16 Aug 2020 19:01:57
User entered 'No (N)'	System	16 Aug 2020 19:01:57

US3792012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:48:26

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-16T12:01:35', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '8223b4c5-63ac-46e8-b1c9-3681fffd52d0'	System	16 Aug 2020 19:01:57
User entered 'None (1)'	System	16 Aug 2020 19:01:57

US3792012
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:48:26
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-16T12:01:55', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '8223b4c5-63ac-46e8-b1c9-3681fffd52d0'	System	16 Aug 2020 19:01:57
User entered '16 Aug 2020 12:01'	System	16 Aug 2020 19:01:57

US3792012
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:48:26
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
User entered '16 Aug 2020 12:00'	System	12 Aug 2020 17:58:39

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
User entered '17 Aug 2020 11:59'	System	12 Aug 2020 17:58:39

FDA-CBER-2022-1614-3381689

US3792012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:48:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
Data entry locked.	System	12 Aug 2020 17:58:39
User entered 'Day 6'	System	12 Aug 2020 17:58:39

US3792012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:48:26

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-17T12:06:06', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '28fb901c-508c-4fac-943a-aea306e23b3b'	System	17 Aug 2020 19:06:28
User entered 'None (1)'	System	17 Aug 2020 19:06:28

FDA-CBER-2022-1614-3381691

US3792012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:48:26

Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-17T12:06:10', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '28fb901c-508c-4fac-943a-aea306e23b3b'	System	17 Aug 2020 19:06:28
User entered 'No (N)'	System	17 Aug 2020 19:06:28

US3792012
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:48:26
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-17T12:06:14', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '28fb901c-508c-4fac-943a-aea306e23b3b'	System	17 Aug 2020 19:06:28
User entered 'No (N)'	System	17 Aug 2020 19:06:28

US3792012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:48:26

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-17T12:06:20', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '28fb901c-508c-4fac-943a-aea306e23b3b'	System	17 Aug 2020 19:06:28
User entered 'None (1)'	System	17 Aug 2020 19:06:28

US3792012
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:48:26
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-17T12:06:26', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '28fb901c-508c-4fac-943a-aea306e23b3b'	System	17 Aug 2020 19:06:28
User entered '17 Aug 2020 12:06'	System	17 Aug 2020 19:06:28

US3792012
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:48:26
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
User entered '17 Aug 2020 12:00'	System	12 Aug 2020 17:58:39

US3792012
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:48:26
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
User entered '18 Aug 2020 11:59'	System	12 Aug 2020 17:58:39

US3792012
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
Data entry locked.	System	12 Aug 2020 17:58:39
User entered 'Day 7'	System	12 Aug 2020 17:58:39

US3792012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:48:26

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-18T13:17:14', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '2c8a78fe-dea2-439a-9cc7-5eda6093b8f5'	System	18 Aug 2020 20:17:34
User entered 'None (1)'	System	18 Aug 2020 20:17:34

US3792012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:48:26

Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-18T13:17:18', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '2c8a78fe-dea2-439a-9cc7-5eda6093b8f5'	System	18 Aug 2020 20:17:34
User entered 'No (N)'	System	18 Aug 2020 20:17:34

US3792012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:48:26

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-18T13:17:21', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '2c8a78fe-dea2-439a-9cc7-5eda6093b8f5'	System	18 Aug 2020 20:17:34
User entered 'No (N)'	System	18 Aug 2020 20:17:34

US3792012

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:48:26

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-18T13:17:25', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '2c8a78fe-dea2-439a-9cc7-5eda6093b8f5'	System	18 Aug 2020 20:17:34
User entered 'None (1)'	System	18 Aug 2020 20:17:34

US3792012
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:48:26
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-18T13:17:30', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '2c8a78fe-dea2-439a-9cc7-5eda6093b8f5'	System	18 Aug 2020 20:17:34
User entered '18 Aug 2020 13:17'	System	18 Aug 2020 20:17:34

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
User entered '18 Aug 2020 12:00'	System	12 Aug 2020 17:58:39

FDA-CBER-2022-1614-3381704

US3792012
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:48:26
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
User entered '19 Aug 2020 11:59'	System	12 Aug 2020 17:58:39

US3792012
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:42:06
Data entry locked.	System	12 Aug 2020 17:58:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Aug 2020 17:58:39

US3792012

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:48:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:42:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-12T11:28:40', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'e1099297-a4ef-4f26-ae71-07108b24e5bf'	System	12 Aug 2020 18:29:36
User entered 'None (0)'	System	12 Aug 2020 18:29:36

US3792012
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:48:26
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:42:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-12T11:28:48', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'e1099297-a4ef-4f26-ae71-07108b24e5bf'	System	12 Aug 2020 18:29:36
User entered 'None (0)'	System	12 Aug 2020 18:29:36

US3792012
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:48:26
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:42:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-12T11:28:53', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'e1099297-a4ef-4f26-ae71-07108b24e5bf'	System	12 Aug 2020 18:29:36
User entered 'None (0)'	System	12 Aug 2020 18:29:36

US3792012
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:48:26
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:42:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-12T11:28:58', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'e1099297-a4ef-4f26-ae71-07108b24e5bf'	System	12 Aug 2020 18:29:36
User entered 'None (0)'	System	12 Aug 2020 18:29:36

US3792012
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:48:26
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:42:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-12T11:29:13', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'e1099297-a4ef-4f26-ae71-07108b24e5bf'	System	12 Aug 2020 18:29:36
User entered 'None (0)'	System	12 Aug 2020 18:29:36

US3792012
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:48:26
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:42:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-12T11:29:18', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'e1099297-a4ef-4f26-ae71-07108b24e5bf'	System	12 Aug 2020 18:29:36
User entered 'None (0)'	System	12 Aug 2020 18:29:36

US3792012

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:48:26

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:42:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-12T11:29:27', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'e1099297-a4ef-4f26-ae71-07108b24e5bf'	System	12 Aug 2020 18:29:36
User entered 'No (N)'	System	12 Aug 2020 18:29:36

US3792012
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:48:26
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:42:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-12T11:29:31', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'e1099297-a4ef-4f26-ae71-07108b24e5bf'	System	12 Aug 2020 18:29:36
User entered '12 Aug 2020 11:29'	System	12 Aug 2020 18:29:36

US3792012
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:48:26
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:42:06
User entered '12 Aug 2020 11:03'	System	12 Aug 2020 17:58:39

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:42:06
User entered '12 Aug 2020 13:33'	System	12 Aug 2020 17:58:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:42:06
Data entry locked.	System	12 Aug 2020 17:58:39
User entered 'Day 1, after vaccination (at home)'	System	12 Aug 2020 17:58:39

US3792012
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:48:26
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:42:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-12T15:46:21', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '0324d7e2-c651-4e71-977c-a3cccbc544ad'	System	12 Aug 2020 22:47:11
User entered 'No interference with activity (1)'	System	12 Aug 2020 22:47:11

US3792012
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:48:26
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:42:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-12T15:46:30', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '0324d7e2-c651-4e71-977c-a3cccbc544ad'	System	12 Aug 2020 22:47:11
User entered 'None (0)'	System	12 Aug 2020 22:47:11

US3792012
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:48:26
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:42:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-12T15:46:44', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '0324d7e2-c651-4e71-977c-a3cccbc544ad'	System	12 Aug 2020 22:47:11
User entered 'No interference with activity (1)'	System	12 Aug 2020 22:47:11

US3792012
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:48:26
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:42:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-12T15:46:48', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '0324d7e2-c651-4e71-977c-a3cccbc544ad'	System	12 Aug 2020 22:47:11
User entered 'No interference with activity (1)'	System	12 Aug 2020 22:47:11

US3792012
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:48:26
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:42:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-12T15:46:53', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '0324d7e2-c651-4e71-977c-a3cccbc544ad'	System	12 Aug 2020 22:47:11
User entered 'None (0)'	System	12 Aug 2020 22:47:11

US3792012

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:48:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:42:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-12T15:46:58', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '0324d7e2-c651-4e71-977c-a3cccbc544ad'	System	12 Aug 2020 22:47:11
User entered 'None (0)'	System	12 Aug 2020 22:47:11

US3792012
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:48:26

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:42:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-12T15:47:06', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '0324d7e2-c651-4e71-977c-a3cccbc544ad'	System	12 Aug 2020 22:47:11
User entered 'No (N)'	System	12 Aug 2020 22:47:11

US3792012

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:48:26

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:42:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-12T15:47:09', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '0324d7e2-c651-4e71-977c-a3cccbc544ad'	System	12 Aug 2020 22:47:11
User entered '12 Aug 2020 15:47'	System	12 Aug 2020 22:47:11

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:42:06
User entered '12 Aug 2020 14:28'	System	12 Aug 2020 17:58:39

FDA-CBER-2022-1614-3381726

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:42:06
User entered '13 Aug 2020 11:59'	System	12 Aug 2020 17:58:39

FDA-CBER-2022-1614-3381727

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:42:06
Data entry locked.	System	12 Aug 2020 17:58:39
User entered 'Day 2'	System	12 Aug 2020 17:58:39

FDA-CBER-2022-1614-3381728

US3792012
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:48:26
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:42:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-13T12:23:28', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '0120f645-3b16-471a-ad23-7fe317e7ccb7'	System	13 Aug 2020 19:24:15
User entered 'No interference with activity (1)'	System	13 Aug 2020 19:24:15

US3792012
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:48:26
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:42:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-13T12:23:37', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '0120f645-3b16-471a-ad23-7fe317e7ccb7'	System	13 Aug 2020 19:24:15
User entered 'Some interference with activity (2)'	System	13 Aug 2020 19:24:15

US3792012

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:48:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:42:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-13T12:23:48', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '0120f645-3b16-471a-ad23-7fe317e7ccb7'	System	13 Aug 2020 19:24:15
User entered 'Some interference with activity (2)'	System	13 Aug 2020 19:24:15

US3792012
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:48:26
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:42:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-13T12:23:54', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '0120f645-3b16-471a-ad23-7fe317e7ccb7'	System	13 Aug 2020 19:24:15
User entered 'No interference with activity (1)'	System	13 Aug 2020 19:24:15

US3792012

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:48:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:42:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-13T12:23:58', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '0120f645-3b16-471a-ad23-7fe317e7ccb7'	System	13 Aug 2020 19:24:15
User entered 'None (0)'	System	13 Aug 2020 19:24:15

US3792012
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:48:26
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:42:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-13T12:24:03', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '0120f645-3b16-471a-ad23-7fe317e7ccb7'	System	13 Aug 2020 19:24:15
User entered 'None (0)'	System	13 Aug 2020 19:24:15

FDA-CBER-2022-1614-3381734

US3792012

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:48:26

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:42:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-13T12:24:10', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '0120f645-3b16-471a-ad23-7fe317e7ccb7'	System	13 Aug 2020 19:24:15
User entered 'No (N)'	System	13 Aug 2020 19:24:15

US3792012

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:48:26

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:42:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-13T12:24:14', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '0120f645-3b16-471a-ad23-7fe317e7ccb7'	System	13 Aug 2020 19:24:15
User entered '13 Aug 2020 12:24'	System	13 Aug 2020 19:24:15

US3792012
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:48:26
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:42:06
User entered '13 Aug 2020 12:00'	System	12 Aug 2020 17:58:39

US3792012

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:48:26

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:42:06
User entered '14 Aug 2020 11:59'	System	12 Aug 2020 17:58:39

US3792012
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:42:06
Data entry locked.	System	12 Aug 2020 17:58:39
User entered 'Day 3'	System	12 Aug 2020 17:58:39

US3792012
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:48:26
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:42:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-14T12:02:27', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'f0cdc60c-b98b-4eaf-a70f-855ef0adf1fd'	System	14 Aug 2020 19:03:07
User entered 'None (0)'	System	14 Aug 2020 19:03:07

US3792012
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:48:26
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:42:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-14T12:02:32', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'f0cdc60c-b98b-4eaf-a70f-855ef0adf1fd'	System	14 Aug 2020 19:03:07
User entered 'None (0)'	System	14 Aug 2020 19:03:07

FDA-CBER-2022-1614-3381741

US3792012
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:48:26
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:42:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-14T12:02:35', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'f0cdc60c-b98b-4eaf-a70f-855ef0adf1fd'	System	14 Aug 2020 19:03:07
User entered 'None (0)'	System	14 Aug 2020 19:03:07

US3792012

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:48:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:42:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-14T12:02:42', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'f0cdc60c-b98b-4eaf-a70f-855ef0adf1fd'	System	14 Aug 2020 19:03:07
User entered 'None (0)'	System	14 Aug 2020 19:03:07

US3792012

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:48:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:42:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-14T12:02:46', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'f0cdc60c-b98b-4eaf-a70f-855ef0adf1fd'	System	14 Aug 2020 19:03:07
User entered 'None (0)'	System	14 Aug 2020 19:03:07

US3792012
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:48:26
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:42:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-14T12:02:52', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'f0cdc60c-b98b-4eaf-a70f-855ef0adf1fd'	System	14 Aug 2020 19:03:07
User entered 'None (0)'	System	14 Aug 2020 19:03:07

US3792012
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:48:26
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:42:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-14T12:02:58', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'f0cdc60c-b98b-4eaf-a70f-855ef0adf1fd'	System	14 Aug 2020 19:03:07
User entered 'No (N)'	System	14 Aug 2020 19:03:07

US3792012
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:48:26
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:42:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-14T12:03:01', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'f0cdc60c-b98b-4eaf-a70f-855ef0adf1fd'	System	14 Aug 2020 19:03:07
User entered '14 Aug 2020 12:03'	System	14 Aug 2020 19:03:07

US3792012

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:48:26

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:42:06
User entered '14 Aug 2020 12:00'	System	12 Aug 2020 17:58:39

US3792012

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:48:26

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:42:06
User entered '15 Aug 2020 11:59'	System	12 Aug 2020 17:58:39

US3792012
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:42:06
Data entry locked.	System	12 Aug 2020 17:58:39
User entered 'Day 4'	System	12 Aug 2020 17:58:39

US3792012
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:48:26
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:42:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-15T12:03:13', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'bb20aaf0-d028-4546-abc5-b6e2533812a2'	System	15 Aug 2020 19:03:38
User entered 'None (0)'	System	15 Aug 2020 19:03:38

US3792012
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:48:26
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:42:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-15T12:03:16', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'bb20aaf0-d028-4546-abc5-b6e2533812a2'	System	15 Aug 2020 19:03:38
User entered 'None (0)'	System	15 Aug 2020 19:03:38

US3792012
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:48:26
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:42:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-15T12:03:20', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'bb20aaf0-d028-4546-abc5-b6e2533812a2'	System	15 Aug 2020 19:03:38
User entered 'None (0)'	System	15 Aug 2020 19:03:38

US3792012

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:48:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:42:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-15T12:03:23', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'bb20aaf0-d028-4546-abc5-b6e2533812a2'	System	15 Aug 2020 19:03:38
User entered 'None (0)'	System	15 Aug 2020 19:03:38

US3792012
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:48:26
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:42:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-15T12:03:26', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'bb20aaf0-d028-4546-abc5-b6e2533812a2'	System	15 Aug 2020 19:03:38
User entered 'None (0)'	System	15 Aug 2020 19:03:38

US3792012
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:48:26
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:42:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-15T12:03:29', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'bb20aaf0-d028-4546-abc5-b6e2533812a2'	System	15 Aug 2020 19:03:38
User entered 'None (0)'	System	15 Aug 2020 19:03:38

US3792012

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:48:26

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:42:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-15T12:03:32', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'bb20aaf0-d028-4546-abc5-b6e2533812a2'	System	15 Aug 2020 19:03:38
User entered 'No (N)'	System	15 Aug 2020 19:03:38

US3792012
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:48:26
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:42:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-15T12:03:36', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'bb20aaf0-d028-4546-abc5-b6e2533812a2'	System	15 Aug 2020 19:03:38
User entered '15 Aug 2020 12:03'	System	15 Aug 2020 19:03:38

US3792012
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:48:26
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:42:06
User entered '15 Aug 2020 12:00'	System	12 Aug 2020 17:58:39

US3792012

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:48:26

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:42:06
User entered '16 Aug 2020 11:59'	System	12 Aug 2020 17:58:39

US3792012
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:42:06
Data entry locked.	System	12 Aug 2020 17:58:39
User entered 'Day 5'	System	12 Aug 2020 17:58:39

US3792012
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:48:26
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:42:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-16T12:02:02', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '284a2360-3bb6-4bcd-93cb-36e8bbabd70c'	System	16 Aug 2020 19:02:41
User entered 'None (0)'	System	16 Aug 2020 19:02:41

US3792012
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:48:26
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:42:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-16T12:02:14', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '284a2360-3bb6-4bcd-93cb-36e8bbabd70c'	System	16 Aug 2020 19:02:41
User entered 'None (0)'	System	16 Aug 2020 19:02:41

US3792012

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:48:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:42:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-16T12:02:17', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '284a2360-3bb6-4bcd-93cb-36e8bbabd70c'	System	16 Aug 2020 19:02:41
User entered 'None (0)'	System	16 Aug 2020 19:02:41

US3792012
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:48:26
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:42:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-16T12:02:22', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '284a2360-3bb6-4bcd-93cb-36e8bbabd70c'	System	16 Aug 2020 19:02:41
User entered 'None (0)'	System	16 Aug 2020 19:02:41

US3792012
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:48:26
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:42:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-16T12:02:27', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '284a2360-3bb6-4bcd-93cb-36e8bbabd70c'	System	16 Aug 2020 19:02:41
User entered 'None (0)'	System	16 Aug 2020 19:02:41

US3792012
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:48:26
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:42:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-16T12:02:30', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '284a2360-3bb6-4bcd-93cb-36e8bbabd70c'	System	16 Aug 2020 19:02:41
User entered 'None (0)'	System	16 Aug 2020 19:02:41

US3792012

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:48:26

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:42:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-16T12:02:36', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '284a2360-3bb6-4bcd-93cb-36e8bbabd70c'	System	16 Aug 2020 19:02:41
User entered 'No (N)'	System	16 Aug 2020 19:02:41

FDA-CBER-2022-1614-3381768

US3792012

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:48:26

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:42:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-16T12:02:39', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '284a2360-3bb6-4bcd-93cb-36e8bbabd70c'	System	16 Aug 2020 19:02:41
User entered '16 Aug 2020 12:02'	System	16 Aug 2020 19:02:41

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:42:06
User entered '16 Aug 2020 12:00'	System	12 Aug 2020 17:58:39

FDA-CBER-2022-1614-3381770

US3792012
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:48:26
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:42:06
User entered '17 Aug 2020 11:59'	System	12 Aug 2020 17:58:39

US3792012
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:42:06
Data entry locked.	System	12 Aug 2020 17:58:39
User entered 'Day 6'	System	12 Aug 2020 17:58:39

US3792012
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:48:26
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:42:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-17T12:06:33', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '20c8cf69-cf9e-4fe9-b943-1c6ad4372113'	System	17 Aug 2020 19:07:09
User entered 'None (0)'	System	17 Aug 2020 19:07:09

US3792012
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:48:26
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:42:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-17T12:06:36', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '20c8cf69-cf9e-4fe9-b943-1c6ad4372113'	System	17 Aug 2020 19:07:09
User entered 'None (0)'	System	17 Aug 2020 19:07:09

US3792012
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:48:26
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:42:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-17T12:06:40', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '20c8cf69-cf9e-4fe9-b943-1c6ad4372113'	System	17 Aug 2020 19:07:09
User entered 'None (0)'	System	17 Aug 2020 19:07:09

US3792012
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:48:26
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:42:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-17T12:06:45', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '20c8cf69-cf9e-4fe9-b943-1c6ad4372113'	System	17 Aug 2020 19:07:09
User entered 'None (0)'	System	17 Aug 2020 19:07:09

US3792012
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:48:26
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:42:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-17T12:06:51', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '20c8cf69-cf9e-4fe9-b943-1c6ad4372113'	System	17 Aug 2020 19:07:09
User entered 'None (0)'	System	17 Aug 2020 19:07:09

US3792012
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:48:26
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:42:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-17T12:06:57', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '20c8cf69-cf9e-4fe9-b943-1c6ad4372113'	System	17 Aug 2020 19:07:09
User entered 'None (0)'	System	17 Aug 2020 19:07:09

US3792012

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:48:26

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:42:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-17T12:07:03', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '20c8cf69-cf9e-4fe9-b943-1c6ad4372113'	System	17 Aug 2020 19:07:09
User entered 'No (N)'	System	17 Aug 2020 19:07:09

US3792012
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:48:26
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:42:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-17T12:07:06', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '20c8cf69-cf9e-4fe9-b943-1c6ad4372113'	System	17 Aug 2020 19:07:09
User entered '17 Aug 2020 12:07'	System	17 Aug 2020 19:07:09

US3792012

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:48:26

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:42:06
User entered '17 Aug 2020 12:00'	System	12 Aug 2020 17:58:39

US3792012
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:48:26
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:42:06
User entered '18 Aug 2020 11:59'	System	12 Aug 2020 17:58:39

US3792012
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:42:06
Data entry locked.	System	12 Aug 2020 17:58:39
User entered 'Day 7'	System	12 Aug 2020 17:58:39

US3792012

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:48:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:42:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-18T13:17:35', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'a388de7e-187d-4b1d-9217-059aeb79728a'	System	18 Aug 2020 20:17:58
User entered 'None (0)'	System	18 Aug 2020 20:17:58

US3792012
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:48:26
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:42:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-18T13:17:38', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'a388de7e-187d-4b1d-9217-059aeb79728a'	System	18 Aug 2020 20:17:58
User entered 'None (0)'	System	18 Aug 2020 20:17:58

US3792012

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:48:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:42:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-18T13:17:41', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'a388de7e-187d-4b1d-9217-059aeb79728a'	System	18 Aug 2020 20:17:58
User entered 'None (0)'	System	18 Aug 2020 20:17:58

US3792012
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:48:26
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:42:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-18T13:17:45', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'a388de7e-187d-4b1d-9217-059aeb79728a'	System	18 Aug 2020 20:17:58
User entered 'None (0)'	System	18 Aug 2020 20:17:58

FDA-CBER-2022-1614-3381787

US3792012

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:48:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:42:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-18T13:17:47', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'a388de7e-187d-4b1d-9217-059aeb79728a'	System	18 Aug 2020 20:17:58
User entered 'None (0)'	System	18 Aug 2020 20:17:58

US3792012
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:48:26
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:42:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-18T13:17:50', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'a388de7e-187d-4b1d-9217-059aeb79728a'	System	18 Aug 2020 20:17:58
User entered 'None (0)'	System	18 Aug 2020 20:17:58

US3792012

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:48:26

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:42:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-18T13:17:53', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'a388de7e-187d-4b1d-9217-059aeb79728a'	System	18 Aug 2020 20:17:58
User entered 'No (N)'	System	18 Aug 2020 20:17:58

US3792012

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:48:26

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:42:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-08-18T13:17:56', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'a388de7e-187d-4b1d-9217-059aeb79728a'	System	18 Aug 2020 20:17:58
User entered '18 Aug 2020 13:17'	System	18 Aug 2020 20:17:58

US3792012
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:48:26

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:42:06
User entered '18 Aug 2020 12:00'	System	12 Aug 2020 17:58:39

US3792012

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:48:26

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 05:42:06
User entered '19 Aug 2020 11:59'	System	12 Aug 2020 17:58:39

US3792012
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:48:26

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:13:24
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 13:56:24
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:32:29
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:01:16
User entered 'Yes (Y)'	Ann Marie Milliken (b) (4)	26 Aug 2020 19:04:35

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:13:24
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 13:56:24
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:32:29
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 21:01:16
User entered '20 Aug 2020'	Ann Marie Milliken (b) (4)	26 Aug 2020 19:04:35

FDA-CBER-2022-1614-3381795

US3792012
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:48:26

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:13:24
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 13:56:24
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:32:29
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 21:01:16
User entered 'Contact Made (CONTACT MADE)'	Ann Marie Milliken (b) (4)	26 Aug 2020 19:04:35

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:13:24
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 13:56:24
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:32:29
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:01:16
User entered empty.	Ann Marie Milliken (b) (4)	26 Aug 2020 19:04:35

US3792012

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:48:26

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:13:24
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 13:56:27
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:32:29
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 21:01:39
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Aug 2020 19:04:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Aug 2020 19:04:45
User entered 'Yes (Y)' reason for change: Data Entry Error	Ann Marie Milliken (b) (4)	26 Aug 2020 19:04:45
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Aug 2020 19:04:40
User entered empty.	Ann Marie Milliken (b) (4)	26 Aug 2020 19:04:40

US3792012
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:48:26
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:13:24
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 13:56:27
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:32:29
User entered '1'	System	26 Aug 2020 19:04:45
User entered empty.	System	26 Aug 2020 19:04:40

US3792012
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:48:26
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:13:24
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 13:56:31
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:32:29
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:02:19
User entered 'Yes (Y)'	Ann Marie Milliken (b) (4)	26 Aug 2020 19:04:58

US3792012
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:48:26
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:13:24
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 13:56:31
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:32:29
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 21:02:19
User entered '26 Aug 2020'	Ann Marie Milliken (b) (4)	26 Aug 2020 19:04:58

US3792012
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:48:26
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:13:24
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 13:56:31
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:32:29
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:02:19
User entered 'Contact Made (CONTACT MADE)'	Ann Marie Milliken (b) (4)	26 Aug 2020 19:04:58

US3792012

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:26

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:13:24
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 13:56:31
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:32:29
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 21:02:19
User entered empty.	Ann Marie Milliken (b) (4)	26 Aug 2020 19:04:58

US3792012
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:48:26

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:13:24
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 13:56:34
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:32:29
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:02:41
User entered 'Yes (Y)'	Ann Marie Milliken (b) (4)	26 Aug 2020 19:05:04

US3792012
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:48:26
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:13:24
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 13:56:34
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:32:29
User entered '1'	System	26 Aug 2020 19:05:04

US3792012
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:48:26

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:13:24
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 21:03:27
User entered 'Yes (Y)'	Ann Marie Milliken (b) (4)	02 Sep 2020 21:54:52

US3792012
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:48:26

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:13:24
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 21:03:27
User entered '2 Sep 2020'	Ann Marie Milliken (b) (4)	02 Sep 2020 21:54:52

US3792012

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:26

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:13:24
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 21:03:27
User entered 'Contact Made (CONTACT MADE)'	Ann Marie Milliken (b) (4)	02 Sep 2020 21:54:52

US3792012

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:26

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:13:24
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 21:03:27
User entered empty.	Ann Marie Milliken (b) (4)	02 Sep 2020 21:54:52

US3792012

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:48:26

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:13:24
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 21:03:35
User entered 'Yes (Y)'	Ann Marie Milliken (b) (4)	02 Sep 2020 21:55:22

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:13:24
User entered '1'	System	02 Sep 2020 21:55:22

US3792012

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:48:26

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:36:10
User entered 'Yes (Y)'	Scarlett Hammett (b) (4) (b) (4)	09 Sep 2020 17:24:34

US3792012

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:48:26

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:36:10
User entered '9 Sep 2020'	Scarlett Hammett (b) (4) (b) (4)	09 Sep 2020 17:24:34

US3792012

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:48:26

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 22:32:16
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:36:10
User entered 'Clinic (Clinic)'	Scarlett Hammett (b) (4) (b) (4)	09 Sep 2020 17:24:34

US3792012
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:48:26
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User entered 'VISIT2'	System	09 Sep 2020 17:24:34

US3792012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:26

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User accepted default value 'Pre-Dose (PREDOSE)'	Scarlett Hammett (b) (4) (b) (4)	09 Sep 2020 18:32:28

US3792012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:26

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:37:45
User entered 'Yes (Y)'	Scarlett Hammett (b) (4)	09 Sep 2020 18:32:28

US3792012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:26

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:37:45
User entered '9 Sep 2020'	Scarlett Hammett (b) (4) (b) (4)	09 Sep 2020 18:32:28

US3792012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:26

Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:37:45
User entered '09:02'	Scarlett Hammett (b) (4) (b) (4)	09 Sep 2020 18:32:28

US3792012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:26

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User entered '9 Sep 2020 09:02'	System	09 Sep 2020 18:32:28

US3792012
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:48:26
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:37:45
User entered '97.9' F	Scarlett Hammett (b) (4) (b) (4)	09 Sep 2020 18:32:28

US3792012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:26

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:37:45
User entered 'Oral (Oral)'	Scarlett Hammett (b) (4) (b) (4)	09 Sep 2020 18:32:28

US3792012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:26

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:37:45
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	09 Sep 2020 18:32:28

US3792012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:26

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:37:45
User entered '73'	Scarlett Hammett (b) (4) (b) (4)	09 Sep 2020 18:32:28

US3792012
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:48:26
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User entered 'bpm'	System	09 Sep 2020 18:32:28

US3792012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:26

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:37:45
User entered '20'	Scarlett Hammett (b) (4) (b) (4)	09 Sep 2020 18:32:28

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User entered 'breaths/min'	System	09 Sep 2020 18:32:28

FDA-CBER-2022-1614-3381827

US3792012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:26

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:37:45
User entered '127'	Scarlett Hammett (b) (4) (b) (4)	09 Sep 2020 18:32:28

US3792012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:26

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User entered 'mmHg'	System	09 Sep 2020 18:32:28

US3792012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:26

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:37:45
User entered '82'	Scarlett Hammett (b) (4) (b) (4)	09 Sep 2020 18:32:28

US3792012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:26

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User entered 'mmHg'	System	09 Sep 2020 18:32:28

US3792012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:26

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User accepted default value 'Post-Dose (POSTDOSE)'	Scarlett Hammett (b) (4) (b) (4)	09 Sep 2020 18:32:28

US3792012
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:48:26
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:37:45
User entered 'Yes (Y)'	Scarlett Hammett (b) (4) (b) (4)	09 Sep 2020 18:32:28

US3792012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:26

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:37:45
User entered '9 Sep 2020'	Scarlett Hammett (b) (4) (b) (4)	09 Sep 2020 18:32:28

US3792012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:26

Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:37:45
User entered '10:17'	Scarlett Hammett (b) (4) (b) (4)	09 Sep 2020 18:32:28

US3792012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:26

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User entered '9 Sep 2020 10:17'	System	09 Sep 2020 18:32:28

US3792012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:26

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:37:45
User entered '97.6' F	Scarlett Hammett (b) (4) (b) (4)	09 Sep 2020 18:32:28

US3792012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:26

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:37:45
User entered 'Oral (Oral)'	Scarlett Hammett (b) (4) (b) (4)	09 Sep 2020 18:32:28

US3792012
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:48:26
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:37:45
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	09 Sep 2020 18:32:28

US3792012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:26

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:37:45
User entered '66'	Scarlett Hammett (b) (4) (b) (4)	09 Sep 2020 18:32:28

US3792012
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:48:26
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User entered 'bpm'	System	09 Sep 2020 18:32:28

US3792012
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:48:26

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:37:45
User entered '16'	Scarlett Hammett (b) (4) (b) (4)	09 Sep 2020 18:32:28

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User entered 'breaths/min'	System	09 Sep 2020 18:32:28

FDA-CBER-2022-1614-3381843

US3792012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:26

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:37:45
User entered '134'	Scarlett Hammett (b) (4) (b) (4)	09 Sep 2020 18:32:28

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User entered 'mmHg'	System	09 Sep 2020 18:32:28

US3792012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:26

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:37:45
User entered '88'	Scarlett Hammett (b) (4) (b) (4)	09 Sep 2020 18:32:28

US3792012

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:26

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User entered 'mmHg'	System	09 Sep 2020 18:32:28

US3792012

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:48:26

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:38:15
User entered 'Yes (Y)'	Scarlett Hammett (b) (4) (b) (4)	09 Sep 2020 18:32:39

US3792012

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:48:26

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:38:15
User entered '9 Sep 2020'	Scarlett Hammett (b) (4) (b) (4)	09 Sep 2020 18:32:39

US3792012
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:48:26
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:38:56
User entered 'Yes (Y)'	Scarlett Hammett (b) (4) (b) (4)	09 Sep 2020 17:24:12

US3792012
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:48:26
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:38:56
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	09 Sep 2020 17:24:12

US3792012

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:48:26

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 22:32:16
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:38:56
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	09 Sep 2020 17:24:12

What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User entered 'MRNA-1273 OR PLACEBO'	System	09 Sep 2020 17:24:12

US3792012

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:48:26

What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:38:56
User entered '9 Sep 2020'	Scarlett Hammett (b) (4) (b) (4)	09 Sep 2020 17:24:12

US3792012

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:48:26

What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:38:56
User entered '09:44'	Scarlett Hammett (b) (4) (b) (4)	09 Sep 2020 17:24:12

US3792012
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:48:26

Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User entered '9 Sep 2020 09:44'	System	09 Sep 2020 17:24:12

US3792012

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:48:26

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:38:56
User entered 'Left Arm (LEFT ARM)'	Scarlett Hammett (b) (4) (b) (4)	09 Sep 2020 17:24:12

US3792012

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:48:26

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:38:56
User entered 'ONCE'	System	09 Sep 2020 17:24:12

US3792012

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:48:26

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User entered 'INTRAMUSCULAR'	System	09 Sep 2020 17:24:12

US3792012

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:48:26

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:39:23
User entered 'Yes (Y)'	Scarlett Hammett (b) (4) (b) (4)	12 Sep 2020 01:25:18

US3792012

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:48:26

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:39:23
User entered '9 Sep 2020'	Scarlett Hammett (b) (4) (b) (4)	12 Sep 2020 01:25:18

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:39:23
User entered '09:06'	Scarlett Hammett (b) (4) (b) (4)	12 Sep 2020 01:25:18

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User entered '9 Sep 2020 09:06'	System	12 Sep 2020 01:25:18

FDA-CBER-2022-1614-3381863

Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab
Generated On: 10 Jun 2021 09:48:26
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:39:33
User entered '9 Sep 2020'	Scarlett Hammett (b) (4) (b) (4)	12 Sep 2020 01:25:40

US3792012

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:48:26

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Scarlett Hammett (b) (4) (b) (4)	12 Sep 2020 01:25:40

US3792012

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:48:26

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:39:33
User entered 'Yes (Y)'	Scarlett Hammett (b) (4) (b) (4)	12 Sep 2020 01:25:40

US3792012

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:48:26

Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:39:33
User entered '09:09'	Scarlett Hammett (b) (4) (b) (4)	12 Sep 2020 01:25:40

US3792012

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:48:26

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User entered '9 Sep 2020 09:09'	System	12 Sep 2020 01:25:40

US3792012

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:48:26

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Scarlett Hammett (b) (4) (b) (4)	12 Sep 2020 01:25:40

US3792012

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:48:26

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:39:33
User entered 'No (N)'	Scarlett Hammett (b) (4) (b) (4)	12 Sep 2020 01:25:40

US3792012

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:48:26

Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:39:33
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	12 Sep 2020 01:25:40

US3792012

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:48:26

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User entered empty.	System	12 Sep 2020 01:25:40

US3792012

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:48:26

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:39:42
User entered 'Yes (Y)'	Scarlett Hammett (b) (4) (b) (4)	09 Sep 2020 17:24:41

US3792012
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:48:26
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User entered '1'	System	09 Sep 2020 17:24:41

US3792012

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:48:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
Data entry locked.	System	09 Sep 2020 17:24:12
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 17:24:12

US3792012

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:48:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-09T10:25:25', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '5d275977-3fe5-4616-bfc2-3db67aae94ae'	System	09 Sep 2020 17:25:47
User entered 'Yes (Y)'	System	09 Sep 2020 17:25:47

US3792012
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:48:26

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-09T10:25:33', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '5d275977-3fe5-4616-bfc2-3db67aae94ae'	System	09 Sep 2020 17:25:47
User entered '97.6'	System	09 Sep 2020 17:25:47

US3792012
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:48:26
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-09T10:25:38', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '5d275977-3fe5-4616-bfc2-3db67aae94ae'	System	09 Sep 2020 17:25:47
User entered 'No (N)'	System	09 Sep 2020 17:25:47

FDA-CBER-2022-1614-3381878

US3792012
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:48:26
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-09T10:25:45', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '5d275977-3fe5-4616-bfc2-3db67aae94ae'	System	09 Sep 2020 17:25:47
User entered '09 Sep 2020 10:25'	System	09 Sep 2020 17:25:47

US3792012
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:48:26
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
User entered '09 Sep 2020 10:04'	System	09 Sep 2020 17:24:12

US3792012
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:48:26
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
User entered '09 Sep 2020 12:34'	System	09 Sep 2020 17:24:12

US3792012
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
Data entry locked.	System	09 Sep 2020 17:24:12
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 17:24:12

US3792012
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:48:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-09T13:29:59', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'c24ae419-3d61-4ba9-a32e-96350f3b8fb5'	System	09 Sep 2020 20:30:19
User entered 'Yes (Y)'	System	09 Sep 2020 20:30:19

US3792012
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:48:26

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-09T13:30:06', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'c24ae419-3d61-4ba9-a32e-96350f3b8fb5'	System	09 Sep 2020 20:30:19
User entered '97.6'	System	09 Sep 2020 20:30:19

US3792012

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:48:26

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-09T13:30:10', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'c24ae419-3d61-4ba9-a32e-96350f3b8fb5'	System	09 Sep 2020 20:30:19
User entered 'No (N)'	System	09 Sep 2020 20:30:19

US3792012
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:48:26
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-09T13:30:16', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'c24ae419-3d61-4ba9-a32e-96350f3b8fb5'	System	09 Sep 2020 20:30:19
User entered '09 Sep 2020 13:30'	System	09 Sep 2020 20:30:19

US3792012

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:48:26

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
User entered '09 Sep 2020 13:29'	System	09 Sep 2020 17:24:12

US3792012

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:48:26

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 17:24:12

US3792012
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
Data entry locked.	System	09 Sep 2020 17:24:12
User entered 'Day 2'	System	09 Sep 2020 17:24:12

US3792012
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:48:26
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-10T14:28:39', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'd310f5ed-29d8-461a-9fdd-d0ae6e7a1298'	System	10 Sep 2020 21:28:54
User entered 'Yes (Y)'	System	10 Sep 2020 21:28:54

FDA-CBER-2022-1614-3381890

US3792012
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:48:26

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-10T14:28:35', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'd310f5ed-29d8-461a-9fdd-d0ae6e7a1298'	System	10 Sep 2020 21:28:54
User entered '97.0'	System	10 Sep 2020 21:28:54

FDA-CBER-2022-1614-3381891

US3792012

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:48:26

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-10T14:28:44', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'd310f5ed-29d8-461a-9fdd-d0ae6e7a1298'	System	10 Sep 2020 21:28:54
User entered 'No (N)'	System	10 Sep 2020 21:28:54

US3792012

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:48:26

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-10T14:28:52', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'd310f5ed-29d8-461a-9fdd-d0ae6e7a1298'	System	10 Sep 2020 21:28:54
User entered '10 Sep 2020 14:28'	System	10 Sep 2020 21:28:54

US3792012
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:48:26
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 17:24:12

US3792012

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:48:26

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 17:24:12

US3792012
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
Data entry locked.	System	09 Sep 2020 17:24:12
User entered 'Day 3'	System	09 Sep 2020 17:24:12

US3792012
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:48:26
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-11T12:10:02', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'd5c09d32-15a3-4463-a831-9e28888e2b7a'	System	11 Sep 2020 19:10:24
User entered 'Yes (Y)'	System	11 Sep 2020 19:10:24

US3792012
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:48:26

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-11T12:10:10', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'd5c09d32-15a3-4463-a831-9e28888e2b7a'	System	11 Sep 2020 19:10:24
User entered '99.7'	System	11 Sep 2020 19:10:24

US3792012

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:48:26

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-11T12:10:16', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'd5c09d32-15a3-4463-a831-9e28888e2b7a'	System	11 Sep 2020 19:10:24
User entered 'No (N)'	System	11 Sep 2020 19:10:24

US3792012
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:48:26
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-11T12:10:23', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'd5c09d32-15a3-4463-a831-9e28888e2b7a'	System	11 Sep 2020 19:10:24
User entered '11 Sep 2020 12:10'	System	11 Sep 2020 19:10:24

US3792012
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:48:26

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 17:24:12

US3792012

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:48:26

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 17:24:12

US3792012
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
Data entry locked.	System	09 Sep 2020 17:24:12
User entered 'Day 4'	System	09 Sep 2020 17:24:12

US3792012
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:48:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-12T17:38:46', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '80437ecc-caef-46d2-9f17-b1aabb5497b8'	System	13 Sep 2020 00:39:09
User entered 'Yes (Y)'	System	13 Sep 2020 00:39:09

US3792012
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:48:26

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-12T17:38:56', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '80437ecc-caef-46d2-9f17-b1aabb5497b8'	System	13 Sep 2020 00:39:09
User entered '97.8'	System	13 Sep 2020 00:39:09

US3792012
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:48:26

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-12T17:39:00', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '80437ecc-caef-46d2-9f17-b1aabb5497b8'	System	13 Sep 2020 00:39:09
User entered 'No (N)'	System	13 Sep 2020 00:39:09

US3792012
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:48:26
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-12T17:39:06', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '80437ecc-caef-46d2-9f17-b1aabb5497b8'	System	13 Sep 2020 00:39:09
User entered '12 Sep 2020 17:39'	System	13 Sep 2020 00:39:09

US3792012

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:48:26

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 17:24:12

US3792012
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:48:26
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 17:24:12

US3792012
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
Data entry locked.	System	09 Sep 2020 17:24:12
User entered 'Day 5'	System	09 Sep 2020 17:24:12

US3792012
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:48:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-13T17:48:16', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'fc1dc17f-79ff-4e79-890c-30cd4f4f66eb'	System	14 Sep 2020 00:48:35
User entered 'Yes (Y)'	System	14 Sep 2020 00:48:35

US3792012

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:48:26

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-13T17:48:22', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'fc1dc17f-79ff-4e79-890c-30cd4f4f66eb'	System	14 Sep 2020 00:48:35
User entered '97.8'	System	14 Sep 2020 00:48:35

US3792012

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:48:26

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-13T17:48:26', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'fc1dc17f-79ff-4e79-890c-30cd4f4f66eb'	System	14 Sep 2020 00:48:35
User entered 'No (N)'	System	14 Sep 2020 00:48:35

US3792012

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:48:26

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-13T17:48:31', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'fc1dc17f-79ff-4e79-890c-30cd4f4f66eb'	System	14 Sep 2020 00:48:35
User entered '13 Sep 2020 17:48'	System	14 Sep 2020 00:48:35

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 17:24:12

US3792012
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:48:26
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 17:24:12

US3792012
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
Data entry locked.	System	09 Sep 2020 17:24:12
User entered 'Day 6'	System	09 Sep 2020 17:24:12

US3792012

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:48:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-14T17:33:05', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '9288e49c-b6ca-4519-be94-635ddbe69264'	System	15 Sep 2020 00:33:19
User entered 'Yes (Y)'	System	15 Sep 2020 00:33:19

US3792012

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:48:26

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-14T17:33:11', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '9288e49c-b6ca-4519-be94-635ddbe69264'	System	15 Sep 2020 00:33:19
User entered '98.0'	System	15 Sep 2020 00:33:19

US3792012

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:48:26

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-14T17:33:14', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '9288e49c-b6ca-4519-be94-635ddbe69264'	System	15 Sep 2020 00:33:19
User entered 'No (N)'	System	15 Sep 2020 00:33:19

US3792012
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:48:26
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-14T17:33:17', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '9288e49c-b6ca-4519-be94-635ddbe69264'	System	15 Sep 2020 00:33:19
User entered '14 Sep 2020 17:33'	System	15 Sep 2020 00:33:19

US3792012
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:48:26
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 17:24:12

US3792012
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:48:26
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 17:24:12

US3792012
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
Data entry locked.	System	09 Sep 2020 17:24:12
User entered 'Day 7'	System	09 Sep 2020 17:24:12

US3792012
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:48:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-15T18:01:22', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'db389f00-b114-4992-8da0-22859029e616'	System	16 Sep 2020 01:01:42
User entered 'Yes (Y)'	System	16 Sep 2020 01:01:42

US3792012
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:48:26

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-15T18:01:28', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'db389f00-b114-4992-8da0-22859029e616'	System	16 Sep 2020 01:01:42
User entered '97.6'	System	16 Sep 2020 01:01:42

US3792012

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:48:26

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-15T18:01:31', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'db389f00-b114-4992-8da0-22859029e616'	System	16 Sep 2020 01:01:42
User entered 'No (N)'	System	16 Sep 2020 01:01:42

US3792012
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:48:26
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-15T18:01:34', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'db389f00-b114-4992-8da0-22859029e616'	System	16 Sep 2020 01:01:42
User entered '15 Sep 2020 18:01'	System	16 Sep 2020 01:01:42

US3792012

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:48:26

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
User entered '15 Sep 2020 12:00'	System	09 Sep 2020 17:24:12

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
User entered '16 Sep 2020 11:59'	System	09 Sep 2020 17:24:12

FDA-CBER-2022-1614-3381930

US3792012

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:48:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
Data entry locked.	System	09 Sep 2020 17:24:12
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 17:24:12

US3792012

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:48:26

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-09T10:26:00', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '735552f3-55ff-4437-a4c3-3017ec5da7f9'	System	09 Sep 2020 17:26:37
User entered 'Does not interfere with activity (2)'	System	09 Sep 2020 17:26:37

US3792012
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:48:26
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-09T10:26:17', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '735552f3-55ff-4437-a4c3-3017ec5da7f9'	System	09 Sep 2020 17:26:37
User entered 'No (N)'	System	09 Sep 2020 17:26:37

US3792012

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:48:26

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-09T10:26:23', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '735552f3-55ff-4437-a4c3-3017ec5da7f9'	System	09 Sep 2020 17:26:37
User entered 'No (N)'	System	09 Sep 2020 17:26:37

US3792012

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:48:26

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-09T10:26:30', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '735552f3-55ff-4437-a4c3-3017ec5da7f9'	System	09 Sep 2020 17:26:37
User entered 'None (1)'	System	09 Sep 2020 17:26:37

US3792012
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:48:26
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-09T10:26:35', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '735552f3-55ff-4437-a4c3-3017ec5da7f9'	System	09 Sep 2020 17:26:37
User entered '09 Sep 2020 10:26'	System	09 Sep 2020 17:26:37

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
User entered '09 Sep 2020 10:04'	System	09 Sep 2020 17:24:12

FDA-CBER-2022-1614-3381937

US3792012

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:48:26

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
User entered '09 Sep 2020 12:34'	System	09 Sep 2020 17:24:12

US3792012
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
Data entry locked.	System	09 Sep 2020 17:24:12
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 17:24:12

US3792012

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:48:26

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-09T13:30:28', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'b212647e-2f66-4802-9a20-334e794e0c99'	System	09 Sep 2020 20:31:24
User entered 'Does not interfere with activity (2)'	System	09 Sep 2020 20:31:24

US3792012
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:48:26
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-09T13:30:35', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'b212647e-2f66-4802-9a20-334e794e0c99'	System	09 Sep 2020 20:31:24
User entered 'No (N)'	System	09 Sep 2020 20:31:24

US3792012
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:48:26
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-09T13:30:39', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'b212647e-2f66-4802-9a20-334e794e0c99'	System	09 Sep 2020 20:31:24
User entered 'Yes (Y)'	System	09 Sep 2020 20:31:24

US3792012

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:48:26

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-09T13:31:02', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'b212647e-2f66-4802-9a20-334e794e0c99'	System	09 Sep 2020 20:31:24
User entered '5'	System	09 Sep 2020 20:31:24

US3792012

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:48:26

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-09T13:31:13', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'b212647e-2f66-4802-9a20-334e794e0c99'	System	09 Sep 2020 20:31:24
User entered 'None (1)'	System	09 Sep 2020 20:31:24

FDA-CBER-2022-1614-3381944

US3792012
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:48:26
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-09T13:31:20', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'b212647e-2f66-4802-9a20-334e794e0c99'	System	09 Sep 2020 20:31:24
User entered '09 Sep 2020 13:31'	System	09 Sep 2020 20:31:24

US3792012
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:48:26

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
User entered '09 Sep 2020 13:29'	System	09 Sep 2020 17:24:12

US3792012
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:48:26
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 17:24:12

US3792012
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
Data entry locked.	System	09 Sep 2020 17:24:12
User entered 'Day 2'	System	09 Sep 2020 17:24:12

US3792012

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:48:26

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-10T14:29:02', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'bfad8f35-8473-4a3c-a2a9-b51f2362d3ea'	System	10 Sep 2020 21:29:32
User entered 'Does not interfere with activity (2)'	System	10 Sep 2020 21:29:32

US3792012
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:48:26
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-10T14:29:10', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'bfad8f35-8473-4a3c-a2a9-b51f2362d3ea'	System	10 Sep 2020 21:29:32
User entered 'No (N)'	System	10 Sep 2020 21:29:32

US3792012

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:48:26

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-10T14:29:18', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'bfad8f35-8473-4a3c-a2a9-b51f2362d3ea'	System	10 Sep 2020 21:29:32
User entered 'No (N)'	System	10 Sep 2020 21:29:32

FDA-CBER-2022-1614-3381951

US3792012
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:48:26

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-10T14:29:25', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'bfad8f35-8473-4a3c-a2a9-b51f2362d3ea'	System	10 Sep 2020 21:29:32
User entered 'Does not interfere with activity (2)'	System	10 Sep 2020 21:29:32

US3792012
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:48:26
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-10T14:29:29', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'bfad8f35-8473-4a3c-a2a9-b51f2362d3ea'	System	10 Sep 2020 21:29:32
User entered '10 Sep 2020 14:29'	System	10 Sep 2020 21:29:32

US3792012
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:48:26
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 17:24:12

US3792012

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:48:26

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 17:24:12

US3792012
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
Data entry locked.	System	09 Sep 2020 17:24:12
User entered 'Day 3'	System	09 Sep 2020 17:24:12

US3792012
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:48:26

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-11T12:10:37', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '2eb06144-5a90-4a1a-99e3-a1575bc098f5'	System	11 Sep 2020 19:10:59
User entered 'Does not interfere with activity (2)'	System	11 Sep 2020 19:10:59

FDA-CBER-2022-1614-3381957

US3792012
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:48:26

Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-11T12:10:41', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '2eb06144-5a90-4a1a-99e3-a1575bc098f5'	System	11 Sep 2020 19:10:59
User entered 'No (N)'	System	11 Sep 2020 19:10:59

FDA-CBER-2022-1614-3381958

US3792012
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:48:26
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-11T12:10:46', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '2eb06144-5a90-4a1a-99e3-a1575bc098f5'	System	11 Sep 2020 19:10:59
User entered 'No (N)'	System	11 Sep 2020 19:10:59

US3792012

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:48:26

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-11T12:10:51', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '2eb06144-5a90-4a1a-99e3-a1575bc098f5'	System	11 Sep 2020 19:10:59
User entered 'Does not interfere with activity (2)'	System	11 Sep 2020 19:10:59

US3792012
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:48:26
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-11T12:10:56', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '2eb06144-5a90-4a1a-99e3-a1575bc098f5'	System	11 Sep 2020 19:10:59
User entered '11 Sep 2020 12:10'	System	11 Sep 2020 19:10:59

US3792012
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:48:26
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 17:24:12

US3792012
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:48:26
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 17:24:12

US3792012
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
Data entry locked.	System	09 Sep 2020 17:24:12
User entered 'Day 4'	System	09 Sep 2020 17:24:12

US3792012
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:48:26
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-12T17:39:16', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'c90f3137-a86a-4e23-81b8-c19fda11631a'	System	13 Sep 2020 00:39:38
User entered 'None (1)'	System	13 Sep 2020 00:39:38

US3792012

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:48:26

Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-12T17:39:21', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'c90f3137-a86a-4e23-81b8-c19fda11631a'	System	13 Sep 2020 00:39:38
User entered 'No (N)'	System	13 Sep 2020 00:39:38

FDA-CBER-2022-1614-3381966

US3792012
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:48:26
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-12T17:39:25', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'c90f3137-a86a-4e23-81b8-c19fda11631a'	System	13 Sep 2020 00:39:38
User entered 'No (N)'	System	13 Sep 2020 00:39:38

FDA-CBER-2022-1614-3381967

US3792012

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:48:26

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-12T17:39:32', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'c90f3137-a86a-4e23-81b8-c19fda11631a'	System	13 Sep 2020 00:39:38
User entered 'Does not interfere with activity (2)'	System	13 Sep 2020 00:39:38

US3792012
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:48:26
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-12T17:39:36', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'c90f3137-a86a-4e23-81b8-c19fda11631a'	System	13 Sep 2020 00:39:38
User entered '12 Sep 2020 17:39'	System	13 Sep 2020 00:39:38

US3792012
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:48:26
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 17:24:12

US3792012
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:48:26
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 17:24:12

US3792012
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
Data entry locked.	System	09 Sep 2020 17:24:12
User entered 'Day 5'	System	09 Sep 2020 17:24:12

US3792012

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:48:26

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-13T17:48:37', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '671459e2-8cbe-4d09-b3ed-4e570355bdfd'	System	14 Sep 2020 00:48:57
User entered 'None (1)'	System	14 Sep 2020 00:48:57

US3792012
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:48:26

Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-13T17:48:41', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '671459e2-8cbe-4d09-b3ed-4e570355bdfd'	System	14 Sep 2020 00:48:57
User entered 'No (N)'	System	14 Sep 2020 00:48:57

US3792012
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:48:26
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-13T17:48:45', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '671459e2-8cbe-4d09-b3ed-4e570355bdfd'	System	14 Sep 2020 00:48:57
User entered 'No (N)'	System	14 Sep 2020 00:48:57

US3792012

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:48:26

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-13T17:48:49', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '671459e2-8cbe-4d09-b3ed-4e570355bdfd'	System	14 Sep 2020 00:48:57
User entered 'None (1)'	System	14 Sep 2020 00:48:57

FDA-CBER-2022-1614-3381976

US3792012
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:48:26
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-13T17:48:52', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '671459e2-8cbe-4d09-b3ed-4e570355bdfd'	System	14 Sep 2020 00:48:57
User entered '13 Sep 2020 17:48'	System	14 Sep 2020 00:48:57

FDA-CBER-2022-1614-3381977

US3792012
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:48:26
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 17:24:12

FDA-CBER-2022-1614-3381978

US3792012
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:48:26
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 17:24:12

US3792012
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
Data entry locked.	System	09 Sep 2020 17:24:12
User entered 'Day 6'	System	09 Sep 2020 17:24:12

US3792012

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:48:26

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-14T17:33:23', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '46743b3e-a26e-4015-aad8-09085fb2b8ec'	System	15 Sep 2020 00:33:41
User entered 'None (1)'	System	15 Sep 2020 00:33:41

US3792012
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:48:26

Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-14T17:33:28', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '46743b3e-a26e-4015-aad8-09085fb2b8ec'	System	15 Sep 2020 00:33:41
User entered 'No (N)'	System	15 Sep 2020 00:33:41

US3792012

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:48:26

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-14T17:33:31', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '46743b3e-a26e-4015-aad8-09085fb2b8ec'	System	15 Sep 2020 00:33:41
User entered 'No (N)'	System	15 Sep 2020 00:33:41

US3792012

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:48:26

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-14T17:33:35', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '46743b3e-a26e-4015-aad8-09085fb2b8ec'	System	15 Sep 2020 00:33:41
User entered 'None (1)'	System	15 Sep 2020 00:33:41

US3792012
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:48:26
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-14T17:33:38', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '46743b3e-a26e-4015-aad8-09085fb2b8ec'	System	15 Sep 2020 00:33:41
User entered '14 Sep 2020 17:33'	System	15 Sep 2020 00:33:41

US3792012

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:48:26

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 17:24:12

US3792012
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:48:26
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 17:24:12

US3792012
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
Data entry locked.	System	09 Sep 2020 17:24:12
User entered 'Day 7'	System	09 Sep 2020 17:24:12

US3792012

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:48:26

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-15T18:01:38', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'a28efb7e-b3fc-4ec7-abb8-b762054d65c8'	System	16 Sep 2020 01:01:55
User entered 'None (1)'	System	16 Sep 2020 01:01:55

US3792012
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:48:26

Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-15T18:01:42', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'a28efb7e-b3fc-4ec7-abb8-b762054d65c8'	System	16 Sep 2020 01:01:55
User entered 'No (N)'	System	16 Sep 2020 01:01:55

US3792012
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:48:26
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-15T18:01:45', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'a28efb7e-b3fc-4ec7-abb8-b762054d65c8'	System	16 Sep 2020 01:01:55
User entered 'No (N)'	System	16 Sep 2020 01:01:55

US3792012

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:48:26

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-15T18:01:49', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'a28efb7e-b3fc-4ec7-abb8-b762054d65c8'	System	16 Sep 2020 01:01:55
User entered 'None (1)'	System	16 Sep 2020 01:01:55

US3792012
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:48:26
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-15T18:01:52', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'a28efb7e-b3fc-4ec7-abb8-b762054d65c8'	System	16 Sep 2020 01:01:55
User entered '15 Sep 2020 18:01'	System	16 Sep 2020 01:01:55

US3792012

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:48:26

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
User entered '15 Sep 2020 12:00'	System	09 Sep 2020 17:24:12

US3792012
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:48:26
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
User entered '16 Sep 2020 11:59'	System	09 Sep 2020 17:24:12

US3792012
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
Data entry locked.	System	09 Sep 2020 17:24:12
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 17:24:12

US3792012
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:48:26
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-09T10:26:41', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '5684024c-8aad-4ccc-a8d3-db1db63f860e'	System	09 Sep 2020 17:27:21
User entered 'None (0)'	System	09 Sep 2020 17:27:21

US3792012
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:48:26
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-09T10:26:46', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '5684024c-8aad-4ccc-a8d3-db1db63f860e'	System	09 Sep 2020 17:27:21
User entered 'None (0)'	System	09 Sep 2020 17:27:21

US3792012

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:48:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-09T10:26:53', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '5684024c-8aad-4ccc-a8d3-db1db63f860e'	System	09 Sep 2020 17:27:21
User entered 'None (0)'	System	09 Sep 2020 17:27:21

US3792012
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:48:26
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-09T10:26:59', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '5684024c-8aad-4ccc-a8d3-db1db63f860e'	System	09 Sep 2020 17:27:21
User entered 'None (0)'	System	09 Sep 2020 17:27:21

US3792012
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:48:26
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-09T10:27:02', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '5684024c-8aad-4ccc-a8d3-db1db63f860e'	System	09 Sep 2020 17:27:21
User entered 'None (0)'	System	09 Sep 2020 17:27:21

US3792012
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:48:26
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-09T10:27:05', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '5684024c-8aad-4ccc-a8d3-db1db63f860e'	System	09 Sep 2020 17:27:21
User entered 'None (0)'	System	09 Sep 2020 17:27:21

US3792012

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:48:26

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-09T10:27:12', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '5684024c-8aad-4ccc-a8d3-db1db63f860e'	System	09 Sep 2020 17:27:21
User entered 'No (N)'	System	09 Sep 2020 17:27:21

US3792012

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:48:26

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-09T10:27:19', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '5684024c-8aad-4ccc-a8d3-db1db63f860e'	System	09 Sep 2020 17:27:21
User entered '09 Sep 2020 10:27'	System	09 Sep 2020 17:27:21

US3792012
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:48:26
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
User entered '09 Sep 2020 10:04'	System	09 Sep 2020 17:24:12

US3792012
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:48:26
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
User entered '09 Sep 2020 12:34'	System	09 Sep 2020 17:24:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
Data entry locked.	System	09 Sep 2020 17:24:12
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 17:24:12

US3792012
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:48:26
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-09T13:31:28', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'c44e81ce-7964-43dc-bbe7-6b50f2026eb2'	System	09 Sep 2020 20:32:10
User entered 'None (0)'	System	09 Sep 2020 20:32:10

US3792012
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:48:26
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-09T13:31:34', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'c44e81ce-7964-43dc-bbe7-6b50f2026eb2'	System	09 Sep 2020 20:32:10
User entered 'None (0)'	System	09 Sep 2020 20:32:10

US3792012
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:48:26
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-09T13:31:39', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'c44e81ce-7964-43dc-bbe7-6b50f2026eb2'	System	09 Sep 2020 20:32:10
User entered 'None (0)'	System	09 Sep 2020 20:32:10

FDA-CBER-2022-1614-3382010

US3792012
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:48:26
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-09T13:31:43', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'c44e81ce-7964-43dc-bbe7-6b50f2026eb2'	System	09 Sep 2020 20:32:10
User entered 'None (0)'	System	09 Sep 2020 20:32:10

US3792012
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:48:26
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-09T13:31:47', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'c44e81ce-7964-43dc-bbe7-6b50f2026eb2'	System	09 Sep 2020 20:32:10
User entered 'None (0)'	System	09 Sep 2020 20:32:10

US3792012
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:48:26
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-09T13:31:51', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'c44e81ce-7964-43dc-bbe7-6b50f2026eb2'	System	09 Sep 2020 20:32:10
User entered 'None (0)'	System	09 Sep 2020 20:32:10

US3792012

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:48:26

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-09T13:32:04', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'c44e81ce-7964-43dc-bbe7-6b50f2026eb2'	System	09 Sep 2020 20:32:10
User entered 'No (N)'	System	09 Sep 2020 20:32:10

US3792012

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:48:26

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-09T13:32:08', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'c44e81ce-7964-43dc-bbe7-6b50f2026eb2'	System	09 Sep 2020 20:32:10
User entered '09 Sep 2020 13:32'	System	09 Sep 2020 20:32:10

US3792012
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:48:26
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
User entered '09 Sep 2020 13:29'	System	09 Sep 2020 17:24:12

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 17:24:12

FDA-CBER-2022-1614-3382017

US3792012
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
Data entry locked.	System	09 Sep 2020 17:24:12
User entered 'Day 2'	System	09 Sep 2020 17:24:12

US3792012
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:48:26
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-10T14:29:35', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'ffadf0eb-b319-4ed2-9e6d-8d939f77458d'	System	10 Sep 2020 21:30:03
User entered 'None (0)'	System	10 Sep 2020 21:30:03

US3792012
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:48:26
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-10T14:29:39', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'ffadf0eb-b319-4ed2-9e6d-8d939f77458d'	System	10 Sep 2020 21:30:03
User entered 'None (0)'	System	10 Sep 2020 21:30:03

US3792012
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:48:26
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-10T14:29:43', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'ffadf0eb-b319-4ed2-9e6d-8d939f77458d'	System	10 Sep 2020 21:30:03
User entered 'None (0)'	System	10 Sep 2020 21:30:03

FDA-CBER-2022-1614-3382021

US3792012

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:48:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-10T14:29:46', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'ffadf0eb-b319-4ed2-9e6d-8d939f77458d'	System	10 Sep 2020 21:30:03
User entered 'None (0)'	System	10 Sep 2020 21:30:03

US3792012
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:48:26
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-10T14:29:48', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'ffadf0eb-b319-4ed2-9e6d-8d939f77458d'	System	10 Sep 2020 21:30:03
User entered 'None (0)'	System	10 Sep 2020 21:30:03

US3792012

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:48:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-10T14:29:51', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'ffadf0eb-b319-4ed2-9e6d-8d939f77458d'	System	10 Sep 2020 21:30:03
User entered 'None (0)'	System	10 Sep 2020 21:30:03

FDA-CBER-2022-1614-3382024

US3792012
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:48:26

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-10T14:29:55', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'ffadf0eb-b319-4ed2-9e6d-8d939f77458d'	System	10 Sep 2020 21:30:03
User entered 'No (N)'	System	10 Sep 2020 21:30:03

US3792012
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:48:26
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-10T14:29:59', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'ffadf0eb-b319-4ed2-9e6d-8d939f77458d'	System	10 Sep 2020 21:30:03
User entered '10 Sep 2020 14:29'	System	10 Sep 2020 21:30:03

US3792012
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:48:26
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 17:24:12

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 17:24:12

FDA-CBER-2022-1614-3382028

US3792012
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
Data entry locked.	System	09 Sep 2020 17:24:12
User entered 'Day 3'	System	09 Sep 2020 17:24:12

US3792012
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:48:26
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-11T12:11:09', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'c820c192-1965-4e2c-b216-5480f6a007d6'	System	11 Sep 2020 19:12:05
User entered 'No interference with activity (1)'	System	11 Sep 2020 19:12:05

US3792012
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:48:26
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-11T12:11:17', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'c820c192-1965-4e2c-b216-5480f6a007d6'	System	11 Sep 2020 19:12:05
User entered 'Some interference with activity (2)'	System	11 Sep 2020 19:12:05

US3792012
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:48:26
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-11T12:11:23', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'c820c192-1965-4e2c-b216-5480f6a007d6'	System	11 Sep 2020 19:12:05
User entered 'No interference with activity (1)'	System	11 Sep 2020 19:12:05

US3792012
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:48:26
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-11T12:11:28', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'c820c192-1965-4e2c-b216-5480f6a007d6'	System	11 Sep 2020 19:12:05
User entered 'No interference with activity (1)'	System	11 Sep 2020 19:12:05

US3792012
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:48:26
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-11T12:11:34', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'c820c192-1965-4e2c-b216-5480f6a007d6'	System	11 Sep 2020 19:12:05
User entered 'None (0)'	System	11 Sep 2020 19:12:05

US3792012
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:48:26
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-11T12:11:40', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'c820c192-1965-4e2c-b216-5480f6a007d6'	System	11 Sep 2020 19:12:05
User entered 'Some interference with activity not requiring medical attention (2)'	System	11 Sep 2020 19:12:05

US3792012

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:48:26

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-11T12:11:52', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'c820c192-1965-4e2c-b216-5480f6a007d6'	System	11 Sep 2020 19:12:05
User entered 'No (N)'	System	11 Sep 2020 19:12:05

US3792012

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:48:26

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-11T12:11:59', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'c820c192-1965-4e2c-b216-5480f6a007d6'	System	11 Sep 2020 19:12:05
User entered '11 Sep 2020 12:11'	System	11 Sep 2020 19:12:05

US3792012

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:48:26

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 17:24:12

US3792012

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:48:26

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 17:24:12

US3792012
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
Data entry locked.	System	09 Sep 2020 17:24:12
User entered 'Day 4'	System	09 Sep 2020 17:24:12

US3792012
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:48:26
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-12T17:39:45', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '9e2340f7-9d10-428a-9f28-444cb6a3b4f0'	System	13 Sep 2020 00:40:28
User entered 'None (0)'	System	13 Sep 2020 00:40:28

US3792012
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:48:26
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-12T17:39:53', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '9e2340f7-9d10-428a-9f28-444cb6a3b4f0'	System	13 Sep 2020 00:40:28
User entered 'None (0)'	System	13 Sep 2020 00:40:28

US3792012
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:48:26
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-12T17:39:56', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '9e2340f7-9d10-428a-9f28-444cb6a3b4f0'	System	13 Sep 2020 00:40:28
User entered 'None (0)'	System	13 Sep 2020 00:40:28

FDA-CBER-2022-1614-3382043

US3792012
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:48:26
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-12T17:40:00', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '9e2340f7-9d10-428a-9f28-444cb6a3b4f0'	System	13 Sep 2020 00:40:28
User entered 'None (0)'	System	13 Sep 2020 00:40:28

FDA-CBER-2022-1614-3382044

US3792012
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:48:26
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-12T17:40:10', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '9e2340f7-9d10-428a-9f28-444cb6a3b4f0'	System	13 Sep 2020 00:40:28
User entered 'None (0)'	System	13 Sep 2020 00:40:28

US3792012

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:48:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-12T17:40:15', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '9e2340f7-9d10-428a-9f28-444cb6a3b4f0'	System	13 Sep 2020 00:40:28
User entered 'None (0)'	System	13 Sep 2020 00:40:28

US3792012
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:48:26

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-12T17:40:23', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '9e2340f7-9d10-428a-9f28-444cb6a3b4f0'	System	13 Sep 2020 00:40:28
User entered 'No (N)'	System	13 Sep 2020 00:40:28

US3792012

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:48:26

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-12T17:40:26', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '9e2340f7-9d10-428a-9f28-444cb6a3b4f0'	System	13 Sep 2020 00:40:28
User entered '12 Sep 2020 17:40'	System	13 Sep 2020 00:40:28

US3792012

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:48:26

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 17:24:12

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 17:24:12

FDA-CBER-2022-1614-3382050

US3792012
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
Data entry locked.	System	09 Sep 2020 17:24:12
User entered 'Day 5'	System	09 Sep 2020 17:24:12

US3792012
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:48:26
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-13T17:48:58', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'f697d0f0-2365-44d7-9c8f-24a1ef2590c4'	System	14 Sep 2020 00:49:26
User entered 'None (0)'	System	14 Sep 2020 00:49:26

US3792012
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:48:26
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-13T17:49:01', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'f697d0f0-2365-44d7-9c8f-24a1ef2590c4'	System	14 Sep 2020 00:49:26
User entered 'None (0)'	System	14 Sep 2020 00:49:26

FDA-CBER-2022-1614-3382053

US3792012
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:48:26
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-13T17:49:05', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'f697d0f0-2365-44d7-9c8f-24a1ef2590c4'	System	14 Sep 2020 00:49:26
User entered 'None (0)'	System	14 Sep 2020 00:49:26

US3792012
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:48:26
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-13T17:49:08', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'f697d0f0-2365-44d7-9c8f-24a1ef2590c4'	System	14 Sep 2020 00:49:26
User entered 'None (0)'	System	14 Sep 2020 00:49:26

FDA-CBER-2022-1614-3382055

US3792012
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:48:26
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-13T17:49:11', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'f697d0f0-2365-44d7-9c8f-24a1ef2590c4'	System	14 Sep 2020 00:49:26
User entered 'None (0)'	System	14 Sep 2020 00:49:26

US3792012
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:48:26
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-13T17:49:14', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'f697d0f0-2365-44d7-9c8f-24a1ef2590c4'	System	14 Sep 2020 00:49:26
User entered 'None (0)'	System	14 Sep 2020 00:49:26

US3792012
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:48:26

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-13T17:49:18', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'f697d0f0-2365-44d7-9c8f-24a1ef2590c4'	System	14 Sep 2020 00:49:26
User entered 'No (N)'	System	14 Sep 2020 00:49:26

US3792012

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:48:26

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-13T17:49:22', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'f697d0f0-2365-44d7-9c8f-24a1ef2590c4'	System	14 Sep 2020 00:49:26
User entered '13 Sep 2020 17:49'	System	14 Sep 2020 00:49:26

US3792012

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:48:26

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 17:24:12

US3792012

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:48:26

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 17:24:12

US3792012
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
Data entry locked.	System	09 Sep 2020 17:24:12
User entered 'Day 6'	System	09 Sep 2020 17:24:12

US3792012
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:48:26
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-14T17:33:44', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '830d6568-906d-4b46-b439-6153747f2826'	System	15 Sep 2020 00:34:09
User entered 'None (0)'	System	15 Sep 2020 00:34:09

US3792012
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:48:26
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-14T17:33:46', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '830d6568-906d-4b46-b439-6153747f2826'	System	15 Sep 2020 00:34:09
User entered 'None (0)'	System	15 Sep 2020 00:34:09

US3792012
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:48:26
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-14T17:33:50', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '830d6568-906d-4b46-b439-6153747f2826'	System	15 Sep 2020 00:34:09
User entered 'None (0)'	System	15 Sep 2020 00:34:09

US3792012
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:48:26
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-14T17:33:52', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '830d6568-906d-4b46-b439-6153747f2826'	System	15 Sep 2020 00:34:09
User entered 'None (0)'	System	15 Sep 2020 00:34:09

US3792012
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:48:26
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-14T17:33:55', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '830d6568-906d-4b46-b439-6153747f2826'	System	15 Sep 2020 00:34:09
User entered 'None (0)'	System	15 Sep 2020 00:34:09

US3792012
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:48:26
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-14T17:33:58', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '830d6568-906d-4b46-b439-6153747f2826'	System	15 Sep 2020 00:34:09
User entered 'None (0)'	System	15 Sep 2020 00:34:09

US3792012
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:48:26

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-14T17:34:02', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '830d6568-906d-4b46-b439-6153747f2826'	System	15 Sep 2020 00:34:09
User entered 'No (N)'	System	15 Sep 2020 00:34:09

US3792012

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:48:26

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-14T17:34:05', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '830d6568-906d-4b46-b439-6153747f2826'	System	15 Sep 2020 00:34:09
User entered '14 Sep 2020 17:34'	System	15 Sep 2020 00:34:09

US3792012

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:48:26

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 17:24:12

US3792012

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:48:26

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 17:24:12

US3792012
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
Data entry locked.	System	09 Sep 2020 17:24:12
User entered 'Day 7'	System	09 Sep 2020 17:24:12

US3792012
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:48:26
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-15T18:02:01', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '2befeda7-fb41-462a-9f0d-989a7adcceb4'	System	16 Sep 2020 01:02:24
User entered 'None (0)'	System	16 Sep 2020 01:02:24

US3792012
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:48:26
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-15T18:02:04', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '2befeda7-fb41-462a-9f0d-989a7adcceb4'	System	16 Sep 2020 01:02:24
User entered 'None (0)'	System	16 Sep 2020 01:02:24

US3792012

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:48:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-15T18:02:07', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '2befeda7-fb41-462a-9f0d-989a7adcceb4'	System	16 Sep 2020 01:02:24
User entered 'None (0)'	System	16 Sep 2020 01:02:24

FDA-CBER-2022-1614-3382076

US3792012
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:48:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-15T18:02:09', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '2befeda7-fb41-462a-9f0d-989a7adcceb4'	System	16 Sep 2020 01:02:24
User entered 'None (0)'	System	16 Sep 2020 01:02:24

US3792012
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:48:26
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-15T18:02:12', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '2befeda7-fb41-462a-9f0d-989a7adcceb4'	System	16 Sep 2020 01:02:24
User entered 'None (0)'	System	16 Sep 2020 01:02:24

US3792012
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:48:26
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-15T18:02:14', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '2befeda7-fb41-462a-9f0d-989a7adcceb4'	System	16 Sep 2020 01:02:24
User entered 'None (0)'	System	16 Sep 2020 01:02:24

US3792012

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:48:26

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-15T18:02:18', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '2befeda7-fb41-462a-9f0d-989a7adcceb4'	System	16 Sep 2020 01:02:24
User entered 'No (N)'	System	16 Sep 2020 01:02:24

US3792012
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:48:26
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-09-15T18:02:21', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '2befeda7-fb41-462a-9f0d-989a7adcceb4'	System	16 Sep 2020 01:02:24
User entered '15 Sep 2020 18:02'	System	16 Sep 2020 01:02:24

US3792012

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:48:26

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
User entered '15 Sep 2020 12:00'	System	09 Sep 2020 17:24:12

US3792012

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:48:26

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
User entered '16 Sep 2020 11:59'	System	09 Sep 2020 17:24:12

US3792012
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:48:26

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:42:56
User entered 'Yes (Y)'	Ann Marie Milliken (b) (4)	16 Sep 2020 18:36:20

US3792012

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:26

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:42:56
User entered '16 Sep 2020'	Ann Marie Milliken (b) (4)	16 Sep 2020 18:36:20

US3792012
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:48:26
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:42:56
User entered 'Contact Made (CONTACT MADE)'	Ann Marie Milliken (b) (4)	16 Sep 2020 18:36:20

US3792012
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:48:26
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:42:56
User entered empty.	Ann Marie Milliken (b) (4)	16 Sep 2020 18:36:20

US3792012
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:48:26

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:43:02
User entered 'Yes (Y)'	Ann Marie Milliken (b) (4)	16 Sep 2020 18:36:25

US3792012

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:48:26

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User entered '1'	System	16 Sep 2020 18:36:25

US3792012
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:48:26

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:43:13
User entered 'Yes (Y)'	Ann Marie Milliken (b) (4)	30 Sep 2020 23:07:31

US3792012

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:26

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:36:29
User closed query 'Per source, safety call day 43 was made on 24Sep2020, EDC states 23Sep2020. Please reconcile. ' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 17:36:26
Query 'Per source, safety call day 43 was made on 24Sep2020, EDC states 23Sep2020. Please reconcile. ' answered with 'UPDATED' (Site from CRA).	Scarlett Hammett (b) (4) (b) (4)	18 Nov 2020 18:51:11
User entered '24 Sep 2020' reason for change: Data Entry Error	Scarlett Hammett (b) (4) (b) (4)	18 Nov 2020 18:51:03
User opened query 'Per source, safety call day 43 was made on 24Sep2020, EDC states 23Sep2020. Please reconcile. ' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 17:31:34
DataPoint Un-verified.	(b) (4), (b) (6)	18 Nov 2020 17:30:18
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:43:13
User entered '23 Sep 2020'	Ann Marie Milliken (b) (4)	30 Sep 2020 23:07:31

US3792012
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:48:26
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:43:13
User entered 'Contact Made (CONTACT MADE)'	Ann Marie Milliken (b) (4)	30 Sep 2020 23:07:31

US3792012

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:26

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:43:13
User entered empty.	Ann Marie Milliken (b) (4)	30 Sep 2020 23:07:31

US3792012
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:48:26

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:43:20
User entered 'Yes (Y)'	Ann Marie Milliken (b) (4)	30 Sep 2020 23:07:35

US3792012
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:48:26
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User entered '1'	System	30 Sep 2020 23:07:35

US3792012
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:48:26

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:08:03
User closed query 'Cannot verify in source. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	06 Nov 2020 16:08:00
Query 'Cannot verify in source. Please reconcile.' answered with 'source has contact page.' (Site from CRA).	Bettie Corcoran (b) (4) (b) (4)	05 Nov 2020 19:56:04
User opened query 'Cannot verify in source. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	08 Oct 2020 15:46:29
User entered 'Yes (Y)'	Ann Marie Milliken (b) (4)	30 Sep 2020 23:07:47

US3792012

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:26

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 21:36:24
User entered '30 Sep 2020'	Ann Marie Milliken (b) (4)	30 Sep 2020 23:07:47

US3792012

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:26

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 21:36:26
User entered 'Contact Made (CONTACT MADE)'	Ann Marie Milliken (b) (4)	30 Sep 2020 23:07:47

US3792012
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:48:26
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:29:13
User entered empty.	Ann Marie Milliken (b) (4)	30 Sep 2020 23:07:47

US3792012
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:48:26
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:10:52
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
User entered 'Yes (Y)'	Ann Marie Milliken (b) (4)	30 Sep 2020 23:07:53

US3792012
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:48:26
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User entered '1'	System	30 Sep 2020 23:07:53

US3792012

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:48:26

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:47:57
User entered 'Yes (Y)'	Scarlett Hammett (b) (4) (b) (4)	07 Oct 2020 16:27:47

US3792012

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:48:26

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:47:57
User entered '7 Oct 2020'	Scarlett Hammett (b) (4) (b) (4)	07 Oct 2020 16:27:47

US3792012

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:48:26

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 22:32:16
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:47:57
User entered 'Clinic (Clinic)'	Scarlett Hammett (b) (4) (b) (4)	07 Oct 2020 16:27:47

US3792012
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:48:26
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User entered 'VISIT3'	System	07 Oct 2020 16:27:47

US3792012
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:48:26
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:49:01
User entered 'Yes (Y)'	Scarlett Hammett (b) (4) (b) (4)	07 Oct 2020 16:29:36

US3792012

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:26

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:49:01
User entered '7 Oct 2020'	Scarlett Hammett (b) (4) (b) (4)	07 Oct 2020 16:29:36

US3792012

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:26

Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:49:01
User entered '08:54'	Scarlett Hammett (b) (4) (b) (4)	07 Oct 2020 16:29:36

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User entered '7 Oct 2020 08:54'	System	07 Oct 2020 16:29:36

FDA-CBER-2022-1614-3382109

US3792012
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:48:26
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:49:01
User entered '97.4' F	Scarlett Hammett (b) (4) (b) (4)	07 Oct 2020 16:29:36

US3792012
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:48:26

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:49:01
User entered 'Oral (Oral)'	Scarlett Hammett (b) (4) (b) (4)	07 Oct 2020 16:29:36

US3792012
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:48:26
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:49:01
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	07 Oct 2020 16:29:36

US3792012
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:48:26
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:49:01
User entered '68'	Scarlett Hammett (b) (4) (b) (4)	07 Oct 2020 16:29:36

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User entered 'bpm'	System	07 Oct 2020 16:29:36

FDA-CBER-2022-1614-3382114

US3792012
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:48:26
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:49:01
User entered '16'	Scarlett Hammett (b) (4) (b) (4)	07 Oct 2020 16:29:36

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User entered 'breaths/min'	System	07 Oct 2020 16:29:36

FDA-CBER-2022-1614-3382116

US3792012

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:26

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:49:01
User entered '143'	Scarlett Hammett (b) (4) (b) (4)	07 Oct 2020 16:29:36

US3792012

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:26

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User entered 'mmHg'	System	07 Oct 2020 16:29:36

US3792012

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:26

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:49:01
User entered '91'	Scarlett Hammett (b) (4) (b) (4)	07 Oct 2020 16:29:36

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User entered 'mmHg'	System	07 Oct 2020 16:29:36

FDA-CBER-2022-1614-3382120

US3792012
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:48:26
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16

US3792012
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:48:26
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16

US3792012

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:48:26

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:49:17
User entered 'Yes (Y)'	Scarlett Hammett (b) (4) (b) (4)	07 Oct 2020 16:30:21

US3792012
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Generated On: 10 Jun 2021 09:48:26
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:49:17
User entered '7 Oct 2020'	Scarlett Hammett (b) (4) (b) (4)	07 Oct 2020 16:30:21

US3792012

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:48:26

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:49:57
User entered 'Yes (Y)'	Scarlett Hammett (b) (4) (b) (4)	07 Oct 2020 16:31:02

US3792012

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:48:26

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:49:57
User entered '7 Oct 2020'	Scarlett Hammett (b) (4) (b) (4)	07 Oct 2020 16:31:02

US3792012

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:48:26

Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 17:30:29
User closed query 'Source states collection time to be 09:01, EDC states 08:54. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	06 Nov 2020 17:30:27
Query 'Source states collection time to be 09:01, EDC states 08:54. Please reconcile.' answered with 'UPDATED' (Site from CRA).	Scarlett Hammett (b) (4) (b) (4)	05 Nov 2020 15:09:43
User entered '09:01' reason for change: Data Entry Error	Scarlett Hammett (b) (4) (b) (4)	05 Nov 2020 15:09:30
User opened query 'Source states collection time to be 09:01, EDC states 08:54. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	08 Oct 2020 15:54:37
DataPoint Un-verified.	(b) (4), (b) (6)	08 Oct 2020 15:50:53
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:49:57
User entered '08:54'	Scarlett Hammett (b) (4) (b) (4)	07 Oct 2020 16:31:02

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User entered '7 Oct 2020 09:01'	System	05 Nov 2020 15:09:30
User entered '7 Oct 2020 08:54'	System	07 Oct 2020 16:31:02

US3792012

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:48:26

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:41:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:54:47
User entered 'Yes (Y)'	Scarlett Hammett (b) (4)	07 Oct 2020 16:31:10
	(b) (4)	

US3792012
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:48:26
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User entered '1'	System	07 Oct 2020 16:31:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
Data entry locked.	System	12 Aug 2020 17:58:39
User entered 'Day 64'	System	12 Aug 2020 17:58:39

FDA-CBER-2022-1614-3382131

US3792012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-10-12T04:54:37', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '528a6664-0180-4956-9b29-1d54d8e23d26'	System	12 Oct 2020 11:55:06
User entered 'No (N)'	System	12 Oct 2020 11:55:06

US3792012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-10-12T04:54:51', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '528a6664-0180-4956-9b29-1d54d8e23d26'	System	12 Oct 2020 11:55:06
User entered 'No (N)'	System	12 Oct 2020 11:55:06

US3792012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-10-12T04:55:04', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '528a6664-0180-4956-9b29-1d54d8e23d26'	System	12 Oct 2020 11:55:06
User entered '12 Oct 2020 04:55:04'	System	12 Oct 2020 11:55:06

US3792012
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
Data entry locked.	System	12 Aug 2020 17:58:39
User entered '12 Oct 2020 00:01'	System	12 Aug 2020 17:58:39

US3792012
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
Data entry locked.	System	12 Aug 2020 17:58:39
User entered '16 Oct 2020 23:59'	System	12 Aug 2020 17:58:39

US3792012
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
Data entry locked.	System	12 Aug 2020 17:58:39
User entered 'Day 71'	System	12 Aug 2020 17:58:39

US3792012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-10-21T15:22:46', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'f2ac3be9-4d44-48fd-ade6-dbfd16854228'	System	21 Oct 2020 22:23:24
User entered 'No (N)'	System	21 Oct 2020 22:23:24

US3792012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-10-21T15:23:07', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'f2ac3be9-4d44-48fd-ade6-dbfd16854228'	System	21 Oct 2020 22:23:24
User entered 'No (N)'	System	21 Oct 2020 22:23:24

US3792012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-10-21T15:23:22', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'f2ac3be9-4d44-48fd-ade6-dbfd16854228'	System	21 Oct 2020 22:23:24
User entered '21 Oct 2020 15:23:22'	System	21 Oct 2020 22:23:24

US3792012
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
Data entry locked.	System	12 Aug 2020 17:58:39
User entered '19 Oct 2020 00:01'	System	12 Aug 2020 17:58:39

US3792012
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
Data entry locked.	System	12 Aug 2020 17:58:39
User entered '23 Oct 2020 23:59'	System	12 Aug 2020 17:58:39

US3792012
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
Data entry locked.	System	12 Aug 2020 17:58:39
User entered 'Day 78'	System	12 Aug 2020 17:58:39

US3792012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-10-26T17:18:17', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '2b475e1a-bfc1-457b-a392-08d02ddd4e4b'	System	27 Oct 2020 00:18:37
User entered 'No (N)'	System	27 Oct 2020 00:18:37

US3792012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-10-26T17:18:26', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '2b475e1a-bfc1-457b-a392-08d02ddd4e4b'	System	27 Oct 2020 00:18:37
User entered 'No (N)'	System	27 Oct 2020 00:18:37

US3792012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-10-26T17:18:34', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '2b475e1a-bfc1-457b-a392-08d02ddd4e4b'	System	27 Oct 2020 00:18:37
User entered '26 Oct 2020 17:18:34'	System	27 Oct 2020 00:18:37

US3792012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
Data entry locked.	System	12 Aug 2020 17:58:39
User entered '26 Oct 2020 00:01'	System	12 Aug 2020 17:58:39

US3792012
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
Data entry locked.	System	12 Aug 2020 17:58:39
User entered '30 Oct 2020 23:59'	System	12 Aug 2020 17:58:39

US3792012
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
Data entry locked.	System	12 Aug 2020 17:58:39
User entered 'Day 92'	System	12 Aug 2020 17:58:39

US3792012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-11-11T12:35:13', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '424d6551-b254-4226-bf61-7369daa03538'	System	11 Nov 2020 19:35:57
User entered 'No (N)'	System	11 Nov 2020 19:35:57

US3792012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-11-11T12:35:36', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '424d6551-b254-4226-bf61-7369daa03538'	System	11 Nov 2020 19:35:57
User entered 'No (N)'	System	11 Nov 2020 19:35:57

FDA-CBER-2022-1614-3382151

US3792012
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-11-11T12:35:54', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '424d6551-b254-4226-bf61-7369daa03538'	System	11 Nov 2020 19:35:57
User entered '11 Nov 2020 12:35:54'	System	11 Nov 2020 19:35:57

US3792012
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
Data entry locked.	System	12 Aug 2020 17:58:39
User entered '09 Nov 2020 00:01'	System	12 Aug 2020 17:58:39

US3792012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
Data entry locked.	System	12 Aug 2020 17:58:39
User entered '13 Nov 2020 23:59'	System	12 Aug 2020 17:58:39

US3792012
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
Data entry locked.	System	12 Aug 2020 17:58:39
User entered 'Day 99'	System	12 Aug 2020 17:58:39

US3792012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-11-18T12:00:26', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '78f4461b-f296-4927-9c1b-9d25f5060b39'	System	18 Nov 2020 19:01:13
User entered 'No (N)'	System	18 Nov 2020 19:01:13

US3792012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-11-18T12:01:01', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '78f4461b-f296-4927-9c1b-9d25f5060b39'	System	18 Nov 2020 19:01:13
User entered 'No (N)'	System	18 Nov 2020 19:01:13

US3792012

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-11-18T12:01:11', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '78f4461b-f296-4927-9c1b-9d25f5060b39'	System	18 Nov 2020 19:01:13
User entered '18 Nov 2020 12:01:11'	System	18 Nov 2020 19:01:13

US3792012
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
Data entry locked.	System	12 Aug 2020 17:58:39
User entered '16 Nov 2020 00:01'	System	12 Aug 2020 17:58:39

US3792012
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:31:58
Data entry locked.	System	12 Aug 2020 17:58:39
User entered '20 Nov 2020 23:59'	System	12 Aug 2020 17:58:39

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '20 Nov 2020 00:01'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '24 Nov 2020 23:59'	System	19 Nov 2020 05:00:21

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26

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 (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-11-27T05:43:26', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'a382c19a-c6c4-4deb-aa1c-51f148e1fa5a'	System	27 Nov 2020 12:43:48
User entered 'No (N)'	System	27 Nov 2020 12:43:48

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

Have you been exposed to someone with 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 (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-11-27T05:43:40', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'a382c19a-c6c4-4deb-aa1c-51f148e1fa5a'	System	27 Nov 2020 12:43:48
User entered 'No (N)'	System	27 Nov 2020 12:43:48

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-11-27T05:43:44', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'a382c19a-c6c4-4deb-aa1c-51f148e1fa5a'	System	27 Nov 2020 12:43:48
User entered '27 Nov 2020 05:43:44'	System	27 Nov 2020 12:43:48

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '27 Nov 2020 00:01'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '01 Dec 2020 23:59'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 05:00:21

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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 (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-12-04T16:08:12', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'c084e88c-80d0-43ac-8356-b26e9e5c989f'	System	04 Dec 2020 23:08:31
User entered 'No (N)'	System	04 Dec 2020 23:08:31

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26

Have you been exposed to someone with 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 (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-12-04T16:08:25', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'c084e88c-80d0-43ac-8356-b26e9e5c989f'	System	04 Dec 2020 23:08:31
User entered 'No (N)'	System	04 Dec 2020 23:08:31

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-12-04T16:08:29', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'c084e88c-80d0-43ac-8356-b26e9e5c989f'	System	04 Dec 2020 23:08:31
User entered '04 Dec 2020 16:08:29'	System	04 Dec 2020 23:08:31

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '04 Dec 2020 00:01'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '08 Dec 2020 23:59'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 05:00:21

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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 (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-12-13T12:01:54', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '1adc9285-acb5-4101-805d-4daf0cc273a5'	System	13 Dec 2020 19:03:19
User entered 'No (N)'	System	13 Dec 2020 19:03:19

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

Have you been exposed to someone with 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 (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-12-13T12:02:04', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '1adc9285-acb5-4101-805d-4daf0cc273a5'	System	13 Dec 2020 19:03:19
User entered 'No (N)'	System	13 Dec 2020 19:03:19

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-12-13T12:02:08', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '1adc9285-acb5-4101-805d-4daf0cc273a5'	System	13 Dec 2020 19:03:19
User entered '13 Dec 2020 12:02:08'	System	13 Dec 2020 19:03:19

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '11 Dec 2020 00:01'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '15 Dec 2020 23:59'	System	19 Nov 2020 05:00:21

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 05:00:21

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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 (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-12-22T12:56:10', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '30441a72-4aeb-46d6-8225-1421d7d878f1'	System	22 Dec 2020 19:56:22
User entered 'No (N)'	System	22 Dec 2020 19:56:22

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

Have you been exposed to someone with 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 (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-12-22T12:56:14', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '30441a72-4aeb-46d6-8225-1421d7d878f1'	System	22 Dec 2020 19:56:22
User entered 'No (N)'	System	22 Dec 2020 19:56:22

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-12-22T12:56:20', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '30441a72-4aeb-46d6-8225-1421d7d878f1'	System	22 Dec 2020 19:56:22
User entered '22 Dec 2020 12:56:20'	System	22 Dec 2020 19:56:22

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '18 Dec 2020 00:01'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '22 Dec 2020 23:59'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 05:00:21

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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 (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-12-27T12:00:21', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'a93cee27-53f7-432c-bade-bc9a86081b68'	System	27 Dec 2020 19:00:52
User entered 'No (N)'	System	27 Dec 2020 19:00:52

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

Have you been exposed to someone with 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 (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-12-27T12:00:44', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'a93cee27-53f7-432c-bade-bc9a86081b68'	System	27 Dec 2020 19:00:52
User entered 'No (N)'	System	27 Dec 2020 19:00:52

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2020-12-27T12:00:48', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'a93cee27-53f7-432c-bade-bc9a86081b68'	System	27 Dec 2020 19:00:52
User entered '27 Dec 2020 12:00:48'	System	27 Dec 2020 19:00:52

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '25 Dec 2020 00:01'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '29 Dec 2020 23:59'	System	19 Nov 2020 05:00:21

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 05:00:21

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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 (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2021-01-03T12:26:41', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '3e7658af-9384-4230-b42e-6e31ccb737b1'	System	03 Jan 2021 19:27:02
User entered 'No (N)'	System	03 Jan 2021 19:27:02

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

Have you been exposed to someone with 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 (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2021-01-03T12:26:51', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '3e7658af-9384-4230-b42e-6e31ccb737b1'	System	03 Jan 2021 19:27:02
User entered 'No (N)'	System	03 Jan 2021 19:27:02

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2021-01-03T12:26:58', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '3e7658af-9384-4230-b42e-6e31ccb737b1'	System	03 Jan 2021 19:27:02
User entered '03 Jan 2021 12:26:58'	System	03 Jan 2021 19:27:02

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '01 Jan 2021 00:01'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '05 Jan 2021 23:59'	System	19 Nov 2020 05:00:21

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 05:00:21

FDA-CBER-2022-1614-3382200

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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 (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2021-01-08T16:39:02', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'dbc81b62-a72d-469d-adf2-964358a0620a'	System	08 Jan 2021 23:39:11
User entered 'No (N)'	System	08 Jan 2021 23:39:11

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26

Have you been exposed to someone with 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 (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2021-01-08T16:39:04', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'dbc81b62-a72d-469d-adf2-964358a0620a'	System	08 Jan 2021 23:39:11
User entered 'No (N)'	System	08 Jan 2021 23:39:11

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2021-01-08T16:39:07', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'dbc81b62-a72d-469d-adf2-964358a0620a'	System	08 Jan 2021 23:39:11
User entered '08 Jan 2021 16:39:07'	System	08 Jan 2021 23:39:11

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '08 Jan 2021 00:01'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '12 Jan 2021 23:59'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 05:00:21

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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 (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2021-01-15T13:06:00', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'f7eeaa11-4b85-4eb0-a353-c8bcecee81de'	System	15 Jan 2021 20:06:13
User entered 'No (N)'	System	15 Jan 2021 20:06:13

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

Have you been exposed to someone with 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 (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2021-01-15T13:06:04', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'f7eeaa11-4b85-4eb0-a353-c8bcecee81de'	System	15 Jan 2021 20:06:13
User entered 'No (N)'	System	15 Jan 2021 20:06:13

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2021-01-15T13:06:08', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'f7eeaa11-4b85-4eb0-a353-c8bcecee81de'	System	15 Jan 2021 20:06:13
User entered '15 Jan 2021 13:06:08'	System	15 Jan 2021 20:06:13

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '15 Jan 2021 00:01'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '19 Jan 2021 23:59'	System	19 Nov 2020 05:00:21

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 05:00:21

FDA-CBER-2022-1614-3382212

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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 (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2021-01-22T13:03:39', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'c9797df7-5b2b-45f3-8a57-aa6913aca5a7'	System	22 Jan 2021 20:03:54
User entered 'No (N)'	System	22 Jan 2021 20:03:54

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

Have you been exposed to someone with 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 (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2021-01-22T13:03:43', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'c9797df7-5b2b-45f3-8a57-aa6913aca5a7'	System	22 Jan 2021 20:03:54
User entered 'No (N)'	System	22 Jan 2021 20:03:54

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2021-01-22T13:03:50', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'c9797df7-5b2b-45f3-8a57-aa6913aca5a7'	System	22 Jan 2021 20:03:54
User entered '22 Jan 2021 13:03:50'	System	22 Jan 2021 20:03:54

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '22 Jan 2021 00:01'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '26 Jan 2021 23:59'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 05:00:21

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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 (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2021-01-29T13:42:03', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '0ff30adc-dd90-4c21-b458-a135a04f94c0'	System	29 Jan 2021 20:42:13
User entered 'No (N)'	System	29 Jan 2021 20:42:13

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

Have you been exposed to someone with 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 (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2021-01-29T13:42:06', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '0ff30adc-dd90-4c21-b458-a135a04f94c0'	System	29 Jan 2021 20:42:13
User entered 'No (N)'	System	29 Jan 2021 20:42:13

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2021-01-29T13:42:10', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '0ff30adc-dd90-4c21-b458-a135a04f94c0'	System	29 Jan 2021 20:42:13
User entered '29 Jan 2021 13:42:10'	System	29 Jan 2021 20:42:13

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '29 Jan 2021 00:01'	System	19 Nov 2020 05:00:21

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '02 Feb 2021 23:59'	System	19 Nov 2020 05:00:21

FDA-CBER-2022-1614-3382223

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 05:00:21

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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 (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2021-02-07T12:00:28', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '2506bb74-3b62-4fe2-9155-e00f93b7376d'	System	07 Feb 2021 19:00:37
User entered 'No (N)'	System	07 Feb 2021 19:00:37

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

Have you been exposed to someone with 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 (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2021-02-07T12:00:30', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '2506bb74-3b62-4fe2-9155-e00f93b7376d'	System	07 Feb 2021 19:00:37
User entered 'No (N)'	System	07 Feb 2021 19:00:37

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2021-02-07T12:00:33', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '2506bb74-3b62-4fe2-9155-e00f93b7376d'	System	07 Feb 2021 19:00:37
User entered '07 Feb 2021 12:00:33'	System	07 Feb 2021 19:00:37

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '05 Feb 2021 00:01'	System	19 Nov 2020 05:00:21

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '09 Feb 2021 23:59'	System	19 Nov 2020 05:00:21

FDA-CBER-2022-1614-3382229

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 05:00:21

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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 (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2021-02-14T12:00:19', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '12f80bfd-34b5-4690-9b5b-27970635a1c3'	System	14 Feb 2021 19:00:44
User entered 'No (N)'	System	14 Feb 2021 19:00:44

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26

Have you been exposed to someone with 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 (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2021-02-14T12:00:22', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '12f80bfd-34b5-4690-9b5b-27970635a1c3'	System	14 Feb 2021 19:00:44
User entered 'No (N)'	System	14 Feb 2021 19:00:44

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2021-02-14T12:00:29', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '12f80bfd-34b5-4690-9b5b-27970635a1c3'	System	14 Feb 2021 19:00:44
User entered '14 Feb 2021 12:00:29'	System	14 Feb 2021 19:00:44

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '12 Feb 2021 00:01'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '16 Feb 2021 23:59'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 05:00:21

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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 (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2021-02-19T04:59:08', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '8890ae3a-1249-4943-b763-795e93633902'	System	19 Feb 2021 11:59:22
User entered 'No (N)'	System	19 Feb 2021 11:59:22

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

Have you been exposed to someone with 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 (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2021-02-19T04:59:15', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '8890ae3a-1249-4943-b763-795e93633902'	System	19 Feb 2021 11:59:22
User entered 'No (N)'	System	19 Feb 2021 11:59:22

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2021-02-19T04:59:20', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '8890ae3a-1249-4943-b763-795e93633902'	System	19 Feb 2021 11:59:22
User entered '19 Feb 2021 04:59:20'	System	19 Feb 2021 11:59:22

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '19 Feb 2021 00:01'	System	19 Nov 2020 05:00:21

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '23 Feb 2021 23:59'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26

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 (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2021-02-26T07:28:24-07:00', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '54862e9f-ca85-44ef-bac1-1075c4ed315e'	System	26 Feb 2021 14:28:37
User entered 'No (N)'	System	26 Feb 2021 14:28:37

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

Have you been exposed to someone with 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 (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2021-02-26T07:28:31-07:00', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '54862e9f-ca85-44ef-bac1-1075c4ed315e'	System	26 Feb 2021 14:28:37
User entered 'No (N)'	System	26 Feb 2021 14:28:37

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2021-02-26T07:28:34-07:00', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '54862e9f-ca85-44ef-bac1-1075c4ed315e'	System	26 Feb 2021 14:28:37
User entered '26 Feb 2021 14:28:34'	System	26 Feb 2021 14:28:37

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '26 Feb 2021 00:01'	System	19 Nov 2020 05:00:21

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '02 Mar 2021 23:59'	System	19 Nov 2020 05:00:21

FDA-CBER-2022-1614-3382247

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 05:00:21

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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 (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2021-03-07T12:00:25-07:00', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'de2f390c-9222-455a-b8db-d29b14a180a3'	System	07 Mar 2021 19:00:40
User entered 'No (N)'	System	07 Mar 2021 19:00:40

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

Have you been exposed to someone with 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 (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2021-03-07T12:00:29-07:00', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'de2f390c-9222-455a-b8db-d29b14a180a3'	System	07 Mar 2021 19:00:40
User entered 'No (N)'	System	07 Mar 2021 19:00:40

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2021-03-07T12:00:36-07:00', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'de2f390c-9222-455a-b8db-d29b14a180a3'	System	07 Mar 2021 19:00:40
User entered '07 Mar 2021 12:00:36'	System	07 Mar 2021 19:00:40

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '05 Mar 2021 00:01'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '09 Mar 2021 23:59'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 05:00:21

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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 (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2021-03-12T06:00:48-07:00', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'e3f8db1a-089b-4f06-9cb1-2add78236e90'	System	12 Mar 2021 13:01:04
User entered 'No (N)'	System	12 Mar 2021 13:01:04

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26

Have you been exposed to someone with 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 (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2021-03-12T06:00:54-07:00', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'e3f8db1a-089b-4f06-9cb1-2add78236e90'	System	12 Mar 2021 13:01:04
User entered 'No (N)'	System	12 Mar 2021 13:01:04

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2021-03-12T06:00:58-07:00', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: 'e3f8db1a-089b-4f06-9cb1-2add78236e90'	System	12 Mar 2021 13:01:04
User entered '12 Mar 2021 06:00:58'	System	12 Mar 2021 13:01:04

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '12 Mar 2021 00:01'	System	19 Nov 2020 05:00:21

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '16 Mar 2021 23:59'	System	19 Nov 2020 05:00:21

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 05:00:21

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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 (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2021-03-19T04:54:45-07:00', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '0cc95a73-7ab1-4890-a6ee-bc9abaf5a367'	System	19 Mar 2021 11:55:01
User entered 'No (N)'	System	19 Mar 2021 11:55:01

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

Have you been exposed to someone with 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 (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2021-03-19T04:54:50-07:00', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '0cc95a73-7ab1-4890-a6ee-bc9abaf5a367'	System	19 Mar 2021 11:55:01
User entered 'No (N)'	System	19 Mar 2021 11:55:01

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2021-03-19T04:54:55-07:00', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '0cc95a73-7ab1-4890-a6ee-bc9abaf5a367'	System	19 Mar 2021 11:55:01
User entered '19 Mar 2021 04:54:55'	System	19 Mar 2021 11:55:01

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '19 Mar 2021 00:01'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '23 Mar 2021 23:59'	System	19 Nov 2020 05:00:21

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 05:00:21

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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 (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2021-03-26T05:39:13-07:00', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '148b3d52-04c5-4270-91a1-4c637b5284fb'	System	26 Mar 2021 12:39:27
User entered 'No (N)'	System	26 Mar 2021 12:39:27

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26

Have you been exposed to someone with 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 (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2021-03-26T05:39:19-07:00', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '148b3d52-04c5-4270-91a1-4c637b5284fb'	System	26 Mar 2021 12:39:27
User entered 'No (N)'	System	26 Mar 2021 12:39:27

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2021-03-26T05:39:23-07:00', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '148b3d52-04c5-4270-91a1-4c637b5284fb'	System	26 Mar 2021 12:39:27
User entered '26 Mar 2021 05:39:23'	System	26 Mar 2021 12:39:27

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '26 Mar 2021 00:01'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '30 Mar 2021 23:59'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 05:00:21

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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 (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2021-04-02T07:21:53-07:00', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '0d91767a-90f1-4e59-b63f-33cacff789b1'	System	02 Apr 2021 14:22:07
User entered 'No (N)'	System	02 Apr 2021 14:22:07

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26

Have you been exposed to someone with 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 (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2021-04-02T07:21:59-07:00', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '0d91767a-90f1-4e59-b63f-33cacff789b1'	System	02 Apr 2021 14:22:07
User entered 'No (N)'	System	02 Apr 2021 14:22:07

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2021-04-02T07:22:02-07:00', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '0d91767a-90f1-4e59-b63f-33cacff789b1'	System	02 Apr 2021 14:22:07
User entered '02 Apr 2021 07:22:02'	System	02 Apr 2021 14:22:07

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '02 Apr 2021 00:01'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '06 Apr 2021 23:59'	System	19 Nov 2020 05:00:21

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26

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 (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2021-04-09T06:13:47-07:00', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '25e1e33b-490c-4232-a122-7192cac719ed'	System	09 Apr 2021 13:14:03
User entered 'No (N)'	System	09 Apr 2021 13:14:03

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

Have you been exposed to someone with 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 (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2021-04-09T06:13:50-07:00', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '25e1e33b-490c-4232-a122-7192cac719ed'	System	09 Apr 2021 13:14:03
User entered 'No (N)'	System	09 Apr 2021 13:14:03

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2021-04-09T06:13:57-07:00', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '25e1e33b-490c-4232-a122-7192cac719ed'	System	09 Apr 2021 13:14:03
User entered '09 Apr 2021 06:13:57'	System	09 Apr 2021 13:14:03

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '09 Apr 2021 00:01'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '13 Apr 2021 23:59'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 05:00:21

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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 (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2021-04-16T05:11:01-07:00', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '39d14331-e4bc-4486-adb7-37271ed20e21'	System	16 Apr 2021 12:11:16
User entered 'No (N)'	System	16 Apr 2021 12:11:16

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

Have you been exposed to someone with 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 (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2021-04-16T05:11:09-07:00', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '39d14331-e4bc-4486-adb7-37271ed20e21'	System	16 Apr 2021 12:11:16
User entered 'No (N)'	System	16 Apr 2021 12:11:16

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2021-04-16T05:11:12-07:00', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '39d14331-e4bc-4486-adb7-37271ed20e21'	System	16 Apr 2021 12:11:16
User entered '16 Apr 2021 05:11:12'	System	16 Apr 2021 12:11:16

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '16 Apr 2021 00:01'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '20 Apr 2021 23:59'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 05:00:21

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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 (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2021-04-23T06:04:56-07:00', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '3044e50b-cf28-4cc1-aa2c-34e5c7b92bed'	System	23 Apr 2021 13:05:07
User entered 'No (N)'	System	23 Apr 2021 13:05:07

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

Have you been exposed to someone with 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 (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2021-04-23T06:05:01-07:00', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '3044e50b-cf28-4cc1-aa2c-34e5c7b92bed'	System	23 Apr 2021 13:05:07
User entered 'No (N)'	System	23 Apr 2021 13:05:07

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2021-04-23T06:05:04-07:00', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '3044e50b-cf28-4cc1-aa2c-34e5c7b92bed'	System	23 Apr 2021 13:05:07
User entered '23 Apr 2021 06:05:04'	System	23 Apr 2021 13:05:07

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '23 Apr 2021 00:01'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '27 Apr 2021 23:59'	System	19 Nov 2020 05:00:21

FDA-CBER-2022-1614-3382295

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 05:00:21

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

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 (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2021-04-30T06:58:47-07:00', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '56f98452-e59c-4bc2-aec6-a41c9d5b54e1'	System	30 Apr 2021 13:58:58
User entered 'No (N)'	System	30 Apr 2021 13:58:58

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26

Have you been exposed to someone with 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 (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2021-04-30T06:58:51-07:00', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '56f98452-e59c-4bc2-aec6-a41c9d5b54e1'	System	30 Apr 2021 13:58:58
User entered 'No (N)'	System	30 Apr 2021 13:58:58

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2021-04-30T06:58:55-07:00', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '56f98452-e59c-4bc2-aec6-a41c9d5b54e1'	System	30 Apr 2021 13:58:58
User entered '30 Apr 2021 06:58:55'	System	30 Apr 2021 13:58:58

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '30 Apr 2021 00:01'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '04 May 2021 23:59'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '07 May 2021 00:01'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '11 May 2021 23:59'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 05:00:21

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '14 May 2021 00:01'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '18 May 2021 23:59'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '21 May 2021 00:01'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '25 May 2021 23:59'	System	19 Nov 2020 05:00:21

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '28 May 2021 00:01'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '01 Jun 2021 23:59'	System	19 Nov 2020 05:00:21

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '04 Jun 2021 00:01'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '08 Jun 2021 23:59'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '11 Jun 2021 00:01'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '15 Jun 2021 23:59'	System	19 Nov 2020 05:00:21

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '18 Jun 2021 00:01'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '22 Jun 2021 23:59'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '25 Jun 2021 00:01'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '29 Jun 2021 23:59'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '02 Jul 2021 00:01'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '06 Jul 2021 23:59'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '09 Jul 2021 00:01'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '13 Jul 2021 23:59'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '16 Jul 2021 00:01'	System	19 Nov 2020 05:00:21

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '20 Jul 2021 23:59'	System	19 Nov 2020 05:00:21

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '23 Jul 2021 00:01'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '27 Jul 2021 23:59'	System	19 Nov 2020 05:00:21

FDA-CBER-2022-1614-3382337

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '30 Jul 2021 00:01'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '03 Aug 2021 23:59'	System	19 Nov 2020 05:00:21

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '06 Aug 2021 00:01'	System	19 Nov 2020 05:00:21

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '10 Aug 2021 23:59'	System	19 Nov 2020 05:00:21

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '13 Aug 2021 00:01'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '17 Aug 2021 23:59'	System	19 Nov 2020 05:00:21

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '20 Aug 2021 00:01'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '24 Aug 2021 23:59'	System	19 Nov 2020 05:00:21

FDA-CBER-2022-1614-3382349

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '27 Aug 2021 00:01'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '31 Aug 2021 23:59'	System	19 Nov 2020 05:00:21

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '03 Sep 2021 00:01'	System	19 Nov 2020 05:00:21

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '07 Sep 2021 23:59'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '10 Sep 2021 00:01'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '14 Sep 2021 23:59'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '17 Sep 2021 00:01'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '21 Sep 2021 23:59'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '24 Sep 2021 00:01'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '28 Sep 2021 23:59'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '01 Oct 2021 00:01'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '05 Oct 2021 23:59'	System	19 Nov 2020 05:00:21

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '08 Oct 2021 00:01'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '12 Oct 2021 23:59'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '15 Oct 2021 00:01'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '19 Oct 2021 23:59'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 05:00:21

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '22 Oct 2021 00:01'	System	19 Nov 2020 05:00:21

FDA-CBER-2022-1614-3382375

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '26 Oct 2021 23:59'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 05:00:21

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '29 Oct 2021 00:01'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '02 Nov 2021 23:59'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '05 Nov 2021 00:01'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '09 Nov 2021 23:59'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '12 Nov 2021 00:01'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '16 Nov 2021 23:59'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '19 Nov 2021 00:01'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '23 Nov 2021 23:59'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '26 Nov 2021 00:01'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '30 Nov 2021 23:59'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '03 Dec 2021 00:01'	System	19 Nov 2020 05:00:21

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '07 Dec 2021 23:59'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '10 Dec 2021 00:01'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '14 Dec 2021 23:59'	System	19 Nov 2020 05:00:21

FDA-CBER-2022-1614-3382397

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '17 Dec 2021 00:01'	System	19 Nov 2020 05:00:21

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '21 Dec 2021 23:59'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '24 Dec 2021 00:01'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '28 Dec 2021 23:59'	System	19 Nov 2020 05:00:21

FDA-CBER-2022-1614-3382403

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '31 Dec 2021 00:01'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '04 Jan 2022 23:59'	System	19 Nov 2020 05:00:21

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '07 Jan 2022 00:01'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '11 Jan 2022 23:59'	System	19 Nov 2020 05:00:21

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '14 Jan 2022 00:01'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '18 Jan 2022 23:59'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '21 Jan 2022 00:01'	System	19 Nov 2020 05:00:21

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '25 Jan 2022 23:59'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 05:00:21

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '28 Jan 2022 00:01'	System	19 Nov 2020 05:00:21

FDA-CBER-2022-1614-3382417

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '01 Feb 2022 23:59'	System	19 Nov 2020 05:00:21

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '04 Feb 2022 00:01'	System	19 Nov 2020 05:00:21

FDA-CBER-2022-1614-3382420

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '08 Feb 2022 23:59'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '11 Feb 2022 00:01'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '15 Feb 2022 23:59'	System	19 Nov 2020 05:00:21

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '18 Feb 2022 00:01'	System	19 Nov 2020 05:00:21

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '22 Feb 2022 23:59'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 05:00:21

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '25 Feb 2022 00:01'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '01 Mar 2022 23:59'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '04 Mar 2022 00:01'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '08 Mar 2022 23:59'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '11 Mar 2022 00:01'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '15 Mar 2022 23:59'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 05:00:21

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '18 Mar 2022 00:01'	System	19 Nov 2020 05:00:21

FDA-CBER-2022-1614-3382438

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '22 Mar 2022 23:59'	System	19 Nov 2020 05:00:21

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '25 Mar 2022 00:01'	System	19 Nov 2020 05:00:21

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '29 Mar 2022 23:59'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 05:00:21

FDA-CBER-2022-1614-3382443

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '01 Apr 2022 00:01'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '05 Apr 2022 23:59'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 05:00:21

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '08 Apr 2022 00:01'	System	19 Nov 2020 05:00:21

FDA-CBER-2022-1614-3382447

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '12 Apr 2022 23:59'	System	19 Nov 2020 05:00:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 05:00:21

FDA-CBER-2022-1614-3382449

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '15 Apr 2022 00:01'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '19 Apr 2022 23:59'	System	19 Nov 2020 05:00:21

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '22 Apr 2022 00:01'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '26 Apr 2022 23:59'	System	19 Nov 2020 05:00:21

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '29 Apr 2022 00:01'	System	19 Nov 2020 05:00:21

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '03 May 2022 23:59'	System	19 Nov 2020 05:00:21

FDA-CBER-2022-1614-3382457

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '06 May 2022 00:01'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '10 May 2022 23:59'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '13 May 2022 00:01'	System	19 Nov 2020 05:00:21

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '17 May 2022 23:59'	System	19 Nov 2020 05:00:21

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '20 May 2022 00:01'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '24 May 2022 23:59'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '27 May 2022 00:01'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '31 May 2022 23:59'	System	19 Nov 2020 05:00:21

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 05:00:21

FDA-CBER-2022-1614-3382470

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '03 Jun 2022 00:01'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '07 Jun 2022 23:59'	System	19 Nov 2020 05:00:21

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 05:00:21

FDA-CBER-2022-1614-3382473

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '10 Jun 2022 00:01'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '14 Jun 2022 23:59'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '17 Jun 2022 00:01'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '21 Jun 2022 23:59'	System	19 Nov 2020 05:00:21

FDA-CBER-2022-1614-3382478

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '24 Jun 2022 00:01'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '28 Jun 2022 23:59'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '01 Jul 2022 00:01'	System	19 Nov 2020 05:00:21

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '05 Jul 2022 23:59'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '08 Jul 2022 00:01'	System	19 Nov 2020 05:00:21

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '12 Jul 2022 23:59'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '15 Jul 2022 00:01'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '19 Jul 2022 23:59'	System	19 Nov 2020 05:00:21

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 05:00:21

FDA-CBER-2022-1614-3382491

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '22 Jul 2022 00:01'	System	19 Nov 2020 05:00:21

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '26 Jul 2022 23:59'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '29 Jul 2022 00:01'	System	19 Nov 2020 05:00:21

FDA-CBER-2022-1614-3382495

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '02 Aug 2022 23:59'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '05 Aug 2022 00:01'	System	19 Nov 2020 05:00:21

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '09 Aug 2022 23:59'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '12 Aug 2022 00:01'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '16 Aug 2022 23:59'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 05:00:21

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '19 Aug 2022 00:01'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '23 Aug 2022 23:59'	System	19 Nov 2020 05:00:21

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '26 Aug 2022 00:01'	System	19 Nov 2020 05:00:21

US3792012

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:26

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '30 Aug 2022 23:59'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '02 Sep 2022 00:01'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '06 Sep 2022 23:59'	System	19 Nov 2020 05:00:21

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '09 Sep 2022 00:01'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '13 Sep 2022 23:59'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '16 Sep 2022 00:01'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '20 Sep 2022 23:59'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '23 Sep 2022 00:01'	System	19 Nov 2020 05:00:21

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '27 Sep 2022 23:59'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '30 Sep 2022 00:01'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '04 Oct 2022 23:59'	System	19 Nov 2020 05:00:21

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '07 Oct 2022 00:01'	System	19 Nov 2020 05:00:21

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '11 Oct 2022 23:59'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '14 Oct 2022 00:01'	System	19 Nov 2020 05:00:21

US3792012
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:48:26
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:00:21
Amendment Manager: User entered '18 Oct 2022 23:59'	System	19 Nov 2020 05:00:21

US3792012

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:48:26

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)	30 Apr 2021 22:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2021-02-28T16:46:06-07:00', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '71e0190c-ec57-4892-a61e-b8e4ebaadaa5'	System	28 Feb 2021 23:46:17
User entered 'No (N)'	System	28 Feb 2021 23:46:17

US3792012

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:48:26

Date & Time of Submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (48A062D1-95B7-4AEC-AD85-56224FF1C078)', Time: '2021-02-28T16:46:15-07:00', User OID: 'PatientReportedOutcome (US3792012)', ODM File OID: '71e0190c-ec57-4892-a61e-b8e4ebaadaa5'	System	28 Feb 2021 23:46:17
User entered '28 Feb 2021 23:46:15'	System	28 Feb 2021 23:46:17

US3792012
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:48:26

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:28:07
User entered 'Yes (Y)'	Ann Marie Milliken (b) (4)	05 Nov 2020 21:22:35

FDA-CBER-2022-1614-3382532

US3792012
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:48:26

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:28:07
User entered '5 Nov 2020'	Ann Marie Milliken (b) (4)	05 Nov 2020 21:22:35

FDA-CBER-2022-1614-3382533

US3792012
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:48:26
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:28:07
User entered 'Contact Made (CONTACT MADE)'	Ann Marie Milliken (b) (4)	05 Nov 2020 21:22:35

US3792012
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:48:26
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:28:07
User entered empty.	Ann Marie Milliken (b) (4)	05 Nov 2020 21:22:35

US3792012

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:48:26

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 17:28:17
User entered 'Yes (Y)'	Ann Marie Milliken (b) (4)	05 Nov 2020 21:22:42

FDA-CBER-2022-1614-3382536

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:32:16
User entered '1'	System	05 Nov 2020 21:22:42

US3792012

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:26

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:19:56
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:17:59
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
User entered 'Yes (Y)'	Ann Marie Milliken (b) (4)	08 Dec 2020 22:14:10

US3792012

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:26

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:19:56
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:17:59
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
User entered '8 Dec 2020'	Ann Marie Milliken (b) (4)	08 Dec 2020 22:14:10

US3792012

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:26

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:19:56
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:17:59
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
User entered 'Contact Made (CONTACT MADE)'	Ann Marie Milliken (b) (4)	08 Dec 2020 22:14:10

US3792012
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:48:26
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:19:56
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:17:59
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
User entered empty.	Ann Marie Milliken (b) (4)	08 Dec 2020 22:14:10

US3792012

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:48:26

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:19:56
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:18:02
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
User entered 'Yes (Y)'	Ann Marie Milliken (b) (4)	08 Dec 2020 22:14:17

US3792012
Folder: Safety Call Day 119 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:48:26
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:19:56
User entered '1'	System	08 Dec 2020 22:14:17

US3792012
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:48:26

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:19:56
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 17:15:49
User entered 'Yes (Y)'	Ann Marie Milliken (b) (4)	08 Jan 2021 17:22:57

US3792012

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:26

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:19:56
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 17:15:49
User entered '6 Jan 2021'	Ann Marie Milliken (b) (4)	08 Jan 2021 17:22:57

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:19:56
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 17:15:49
User entered 'Contact Made (CONTACT MADE)'	Ann Marie Milliken (b) (4)	08 Jan 2021 17:22:57

US3792012

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:26

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:19:56
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 17:15:49
User entered empty.	Ann Marie Milliken (b) (4)	08 Jan 2021 17:22:57

US3792012
Folder: Safety Call Day 149 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:48:26

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:19:56
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 17:15:59
User entered 'Yes (Y)'	Ann Marie Milliken (b) (4)	08 Jan 2021 17:23:04

US3792012
Folder: Safety Call Day 149 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:48:26
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:19:56
User entered '1'	System	08 Jan 2021 17:23:04

US3792012
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:48:26

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:19:56
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:07:20
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
User entered 'Yes (Y)'	Ann Marie Milliken (b) (4)	19 Mar 2021 20:43:38

US3792012
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:48:26

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:19:56
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:07:20
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
User entered '5 Feb 2021'	Ann Marie Milliken (b) (4)	19 Mar 2021 20:43:38

FDA-CBER-2022-1614-3382551

US3792012

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:26

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:19:56
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:07:20
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
User entered 'Contact Made (CONTACT MADE)'	Ann Marie Milliken (b) (4)	19 Mar 2021 20:43:38

US3792012
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:48:26
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:19:56
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:07:20
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
User entered empty.	Ann Marie Milliken (b) (4)	19 Mar 2021 20:43:38

US3792012

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:48:26

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:19:56
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:07:24
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
User entered 'Yes (Y)'	Ann Marie Milliken (b) (4)	19 Mar 2021 20:43:44

US3792012
Folder: Safety Call Day 179 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:48:26
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:19:56
User entered '1'	System	19 Mar 2021 20:43:44

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:40:59
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:14:57
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:41:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:51:44

FDA-CBER-2022-1614-3382556

US3792012
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:48:26
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:40:59
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:14:57
User closed query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	06 Apr 2021 03:07:15
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
Query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' answered with 'out of window visit +2 days' (Site from System).	(b) (4), (b) (6)	24 Mar 2021 20:53:07
User opened query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	System	24 Mar 2021 20:51:44
User entered '24 Mar 2021'	(b) (4), (b) (6)	24 Mar 2021 20:51:44

US3792012

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:48:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:40:59
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:14:57
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:41:01
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	24 Mar 2021 20:51:44

US3792012
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:48:26
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:40:59
User entered 'VISIT4'	System	24 Mar 2021 20:51:44

US3792012
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:48:26
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:40:59
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:15:14
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	30 Mar 2021 19:28:51

US3792012

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:26

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:40:59
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:15:14
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
User entered '24 Mar 2021'	Norma Frederick (b) (4) (b) (4)	30 Mar 2021 19:28:51

FDA-CBER-2022-1614-3382561

US3792012
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:48:26

Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:40:59
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:15:14
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
User entered '09:37'	Norma Frederick (b) (4) (b) (4)	30 Mar 2021 19:28:51

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:40:59
User entered '24 Mar 2021 09:37'	System	30 Mar 2021 19:28:51

FDA-CBER-2022-1614-3382563

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:40:59
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	08 Apr 2021 22:49:29
User closed query 'per source, Temp is 98.2, EDC states 98.7. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 22:43:18
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 22:43:06
Query 'per source, Temp is 98.2, EDC states 98.7. Please reconcile.' answered with 'EDC updated' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 23:01:29
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 23:01:17
User entered '98.2' F reason for change: Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 23:01:17
User opened query 'per source, Temp is 98.2, EDC states 98.7. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 18:15:59
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 18:15:17
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:15:14
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
User entered '98.7' F	Norma Frederick (b) (4) (b) (4)	30 Mar 2021 19:28:51

US3792012
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:48:26
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:40:59
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:15:14
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
User entered 'Oral (Oral)'	Norma Frederick (b) (4) (b) (4)	30 Mar 2021 19:28:51

US3792012
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:48:26
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:40:59
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:15:14
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
User entered empty.	Norma Frederick (b) (4) (b) (4)	30 Mar 2021 19:28:51

US3792012
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:48:26
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:40:59
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:15:14
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
User entered '78'	Norma Frederick (b) (4) (b) (4)	30 Mar 2021 19:28:51

US3792012
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:48:26
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:40:59
User entered 'bpm'	System	30 Mar 2021 19:28:51

US3792012

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:26

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:40:59
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:15:14
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
User entered '16'	Norma Frederick (b) (4) (b) (4)	30 Mar 2021 19:28:51

US3792012
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:48:26
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:40:59
User entered 'breaths/min'	System	30 Mar 2021 19:28:51

US3792012
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:48:26
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:40:59
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:15:14
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
User entered '131'	Norma Frederick (b) (4) (b) (4)	30 Mar 2021 19:28:51

US3792012
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:48:26
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:40:59
User entered 'mmHg'	System	30 Mar 2021 19:28:51

US3792012

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:26

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:40:59
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:15:14
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
User entered '80'	Norma Frederick (b) (4) (b) (4)	30 Mar 2021 19:28:51

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:40:59
User entered 'mmHg'	System	30 Mar 2021 19:28:51

FDA-CBER-2022-1614-3382574

US3792012
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:48:26
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:40:59

US3792012
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:48:26
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:40:59

US3792012

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:48:26

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:40:59
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:16:25
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:41:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:53:14

US3792012

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:48:26

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:40:59
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:16:25
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:41:01
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:53:14

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:40:59
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:16:59
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:41:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:53:34

FDA-CBER-2022-1614-3382579

US3792012

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:48:26

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:40:59
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:16:59
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
User entered '24 Mar 2021'	(b) (4), (b) (6)	24 Mar 2021 20:53:34

US3792012

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:48:26

Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:40:59
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:16:59
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:41:01
User entered '09:45'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:53:34

US3792012

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:48:26

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:40:59
User entered '24 Mar 2021 09:45'	System	24 Mar 2021 20:53:34

US3792012
Folder: Visit 4 Day 209 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:48:26

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:40:59
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:17:07
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:41:01
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Mar 2021 20:53:44
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Mar 2021 20:53:44
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Mar 2021 20:53:44
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Mar 2021 20:53:37
User entered empty.	(b) (4), (b) (6)	24 Mar 2021 20:53:37

US3792012

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:48:26

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:40:59
User entered '1'	System	24 Mar 2021 20:53:44
User entered empty.	System	24 Mar 2021 20:53:37

US3792012

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:26

Was Contact Attempted?

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	08 Apr 2021 22:49:29
User entered 'Yes (Y)'	Ann Marie Milliken (b) (4)	07 Apr 2021 20:37:23

US3792012

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:26

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	08 Apr 2021 22:49:29
User entered '7 Apr 2021'	Ann Marie Milliken (b) (4)	07 Apr 2021 20:37:23

US3792012
Folder: Safety Call Day 239 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:48:26
Please select one status for the follow-up contact

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	08 Apr 2021 22:49:29
User entered 'Contact Made (CONTACT MADE)'	Ann Marie Milliken (b) (4)	07 Apr 2021 20:37:23

US3792012
Folder: Safety Call Day 239 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:48:26
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	08 Apr 2021 22:49:29
User entered empty.	Ann Marie Milliken (b) (4)	07 Apr 2021 20:37:23

US3792012

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:48:26

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	08 Apr 2021 22:49:29
User entered 'Yes (Y)'	Ann Marie Milliken (b) (4)	07 Apr 2021 20:37:29

US3792012
Folder: Safety Call Day 239 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:48:26
Continuing Flag

Audit	User	Time (GMT)
User entered '1'	System	07 Apr 2021 20:37:29

US3792012
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:48:26

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:04
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:57:52
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	06 Jan 2021 20:29:18

US3792012
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:48:26

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:04
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:57:52
User entered '6 Jan 2021'	Norma Frederick (b) (4) (b) (4)	06 Jan 2021 20:29:18

US3792012
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:48:26

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 11:20:04
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:57:52
User entered 'Clinic (Clinic)'	Norma Frederick (b) (4) (b) (4)	06 Jan 2021 20:29:18

US3792012
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:48:26
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:04
User entered 'UNBLND_DECIDE'	System	06 Jan 2021 20:29:18

Date of updated informed consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:04
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:08:59
User entered '6 Jan 2021'	Norma Frederick (b) (4) (b) (4)	06 Jan 2021 20:29:44

FDA-CBER-2022-1614-3382595

US3792012

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

Form: Unblinding

Generated On: 10 Jun 2021 09:48:26

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:04
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 12:21:54

US3792012

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

Form: Unblinding

Generated On: 10 Jun 2021 09:48:26

Was the participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:04
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 17:08:59
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	06 Jan 2021 20:29:44

US3792012

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

Form: Unblinding

Generated On: 10 Jun 2021 09:48:26

Under what version of the Protocol was the Participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:04
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 12:21:54

US3792012

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

Form: Unblinding

Generated On: 10 Jun 2021 09:48:26

Date of unblinding *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:04
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:08:59
User entered '6 Jan 2021'	Norma Frederick (b) (4) (b) (4)	06 Jan 2021 20:29:44

US3792012

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

Form: Unblinding

Generated On: 10 Jun 2021 09:48:26

Participant randomization assignment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:04
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:08:59
User entered 'mRNA-1273 (mRNA-1273)'	Norma Frederick (b) (4) (b) (4)	06 Jan 2021 20:29:44

US3792012

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

Form: Unblinding

Generated On: 10 Jun 2021 09:48:26

Actual Dose 1

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:04
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:08:59
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	System	20 Jan 2021 07:04:57
User entered 'mRNA-1273 (mRNA-1273)'	Norma Frederick (b) (4) (b) (4)	06 Jan 2021 20:29:44

US3792012

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

Form: Unblinding

Generated On: 10 Jun 2021 09:48:26

Actual Dose 2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:04
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:08:59
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	System	20 Jan 2021 07:04:57
User entered 'mRNA-1273 (mRNA-1273)'	Norma Frederick (b) (4) (b) (4)	06 Jan 2021 20:29:44

US3792012

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

Form: Unblinding

Generated On: 10 Jun 2021 09:48:26

Will participant receive mRNA-1273?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:04
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:08:59
User entered 'No (N)'	Norma Frederick (b) (4)	06 Jan 2021 20:29:44

Placebo Only Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:04
User entered empty.	System	06 Jan 2021 20:29:44

US3792012
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 09:48:26
Continuing with mRNA-1273

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:04
User entered empty.	System	06 Jan 2021 20:29:44

US3792012

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:48:26

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:04
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 17:11:33
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	06 Jan 2021 20:31:49

US3792012

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:48:26

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:04
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:11:33
Query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an Immunogenicity Assessment sample collected on 06JAN2020 for the Participant Decision Visit, however, the Collection Date recorded here is 06JAN2021. Please confirm the correct Collection Date in the query response and update if appropriate.' canceled (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 13:16:19
User opened query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an Immunogenicity Assessment sample collected on 06JAN2020 for the Participant Decision Visit, however, the Collection Date recorded here is 06JAN2021. Please confirm the correct Collection Date in the query response and update if appropriate.' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 19:12:22
User entered '6 Jan 2021'	Norma Frederick (b) (4) (b) (4)	06 Jan 2021 20:31:49

US3792012

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:48:26

Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:04
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:11:33
User entered '13:05'	Norma Frederick (b) (4) (b) (4)	06 Jan 2021 20:31:49

US3792012

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:48:26

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:04
User entered '6 Jan 2021 13:05'	System	06 Jan 2021 20:31:49

US3792012

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:48:26

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:04
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 17:11:42
User entered 'Yes (Y)'	Norma Frederick (b) (4) (b) (4)	06 Jan 2021 20:34:46

US3792012

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:48:26

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:04
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:11:42
User entered '6 Jan 2021'	Norma Frederick (b) (4)	06 Jan 2021 20:34:46

US3792012

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:48:26

Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:04
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 17:11:42
User entered '13:09'	Norma Frederick (b) (4) (b) (4)	06 Jan 2021 20:34:46

US3792012

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:48:26

Collection Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:20:04
User entered '6 Jan 2021 13:09'	System	06 Jan 2021 20:34:46

US3792012

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:48:26

Did the participant experience any adverse events?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:54:01
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:56:04
User entered 'Yes (Y)' reason for change: Data Entry Error	Bettie Corcoran (b) (4) (b) (4)	25 Sep 2020 21:27:07
User entered 'No (N)'	Scarlett Hammett (b) (4) (b) (4)	12 Sep 2020 01:25:52

US3792012
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:48:26
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:12:37

US3792012
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:48:26
Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:12:37
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
User closed query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 20:30:20
Query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' answered with 'confirmed' (Site from DM).	Bettie Corcoran (b) (4) (b) (4)	05 Nov 2020 19:55:05
User opened query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6)	17 Oct 2020 14:58:10
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:57:45
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Diarrhoea (excl infective), PT: Diarrhoea, LLT: Diarrhea - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Sep 2020 21:29:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Sep 2020 21:29:55
Data point term sent to Coder	System	25 Sep 2020 21:29:20
User entered 'diarrhea'	Bettie Corcoran (b) (4) (b) (4)	25 Sep 2020 21:28:25

US3792012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:26

Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:12:37
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:57:45
User entered 'No (N)'	Bettie Corcoran (b) (4) (b) (4)	25 Sep 2020 21:28:25

US3792012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:26

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:12:37
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:57:45
User entered 'No (N)'	Bettie Corcoran (b) (4) (b) (4)	25 Sep 2020 21:28:25

US3792012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:26

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:12:37
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:57:45
User entered 'No (N)'	Bettie Corcoran (b) (4)	25 Sep 2020 21:28:25

US3792012
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:48:26

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:12:37
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:57:45
User entered '21 Sep 2020'	Bettie Corcoran (b) (4) (b) (4)	25 Sep 2020 21:28:25

US3792012
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:48:26

Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:12:37
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:57:45
User entered empty.	Bettie Corcoran (b) (4) (b) (4)	25 Sep 2020 21:28:25

US3792012
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:48:26
AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:12:37
User entered empty.	System	25 Sep 2020 21:28:25

US3792012
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:48:26
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:12:37
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:57:45
User entered 'No (N)'	Bettie Corcoran (b) (4) (b) (4)	25 Sep 2020 21:28:25

US3792012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:12:37
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:57:45
User entered '23 Sep 2020'	Bettie Corcoran (b) (4)	25 Sep 2020 21:28:25

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:12:37
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:57:45
User entered empty.	Bettie Corcoran (b) (4) (b) (4)	25 Sep 2020 21:28:25

FDA-CBER-2022-1614-3382625

US3792012
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:48:26
AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:12:37
User entered empty.	System	25 Sep 2020 21:28:25

US3792012
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:48:26
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:12:37
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:57:45
User entered 'Grade 1/Mild (Grade 1/Mild)'	Bettie Corcoran (b) (4) (b) (4)	25 Sep 2020 21:28:25

US3792012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:26

Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:12:37
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:57:45
User entered 'No (N)'	Bettie Corcoran (b) (4) (b) (4)	25 Sep 2020 21:28:25

US3792012
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:48:26
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:12:37
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:57:45
User entered '0'	Bettie Corcoran (b) (4) (b) (4)	25 Sep 2020 21:28:25

US3792012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:26

Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:12:37
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:57:45
User entered '0'	Bettie Corcoran (b) (4) (b) (4)	25 Sep 2020 21:28:25

US3792012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:26

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:12:37
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:57:45
User entered '0'	Bettie Corcoran (b) (4) (b) (4)	25 Sep 2020 21:28:25

US3792012
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:48:26

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:12:37
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:57:45
User entered empty.	Bettie Corcoran (b) (4) (b) (4)	25 Sep 2020 21:28:25

US3792012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:26

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:12:37
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:57:45
User entered empty.	Bettie Corcoran (b) (4) (b) (4)	25 Sep 2020 21:28:25

US3792012
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:48:26
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:12:37
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:57:45
User entered empty.	Bettie Corcoran (b) (4) (b) (4)	25 Sep 2020 21:28:25

US3792012
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:48:26
Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:12:37
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:57:45
User entered empty.	Bettie Corcoran (b) (4) (b) (4)	25 Sep 2020 21:28:25

US3792012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:26

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:12:37
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:57:45
User entered '0'	Bettie Corcoran (b) (4) (b) (4)	25 Sep 2020 21:28:25

US3792012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:26

Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:12:37
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:57:45
User entered '0'	Bettie Corcoran (b) (4) (b) (4)	25 Sep 2020 21:28:25

US3792012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:26

Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:12:37
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:57:45
User entered '0'	Bettie Corcoran (b) (4) (b) (4)	25 Sep 2020 21:28:25

US3792012
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:48:26
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:12:37
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:57:45
User entered 'Not Related (NOT RELATED)'	Bettie Corcoran (b) (4) (b) (4)	25 Sep 2020 21:28:25

US3792012
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:48:26
Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:12:37
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:57:45
User entered 'Not Related (NOT RELATED)'	Bettie Corcoran (b) (4) (b) (4)	25 Sep 2020 21:28:25

US3792012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:26

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:12:37
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:57:45
User closed query 'Per CDM: As per CCGs p.33, Not Applicable is to be entered only if AE started before first dose or started after last dose and when it started and ended during a time period when study dose was interrupted (not given/held). Please review and reconcile. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 08:52:13
Query 'Per CDM: As per CCGs p.33, Not Applicable is to be entered only if AE started before first dose or started after last dose and when it started and ended during a time period when study dose was interrupted (not given/held). Please review and reconcile. ' answered with 'corrected' (Site from DM).	Bettie Corcoran (b) (4) (b) (4)	02 Oct 2020 19:22:11
User entered 'None (NONE)' reason for change: Data Entry Error	Bettie Corcoran (b) (4) (b) (4)	02 Oct 2020 19:22:05
User opened query 'Per CDM: As per CCGs p.33, Not Applicable is to be entered only if AE started before first dose or started after last dose and when it started and ended during a time period when study dose was interrupted (not given/held). Please review and reconcile. ' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 03:49:18
Query 'Per CDM: As per CCGs p.33, Not Applicable is to be entered only if AE started before first dose or started after last dose and when started and ended during a time period when study dose was interrupted (not given/held). Please review and reconcile. ' canceled (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 03:48:53
User opened query 'Per CDM: As per CCGs p.33, Not Applicable is to be entered only if AE started before first dose or started after last dose and when started and ended during a time period when study dose was interrupted (not given/held). Please review and reconcile. ' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 03:48:16

FDA-CBER-2022-1614-3382641

US3792012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:26

Action taken with investigational product

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Bettie Corcoran (b) (4)	25 Sep 2020 21:28:25
	(b) (4)	

US3792012
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:48:26
None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:12:37
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:57:45
User entered '1'	Bettie Corcoran (b) (4)	25 Sep 2020 21:28:25

US3792012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:26

Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:12:37
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:57:45
User entered '0'	Bettie Corcoran (b) (4) (b) (4)	25 Sep 2020 21:28:25

US3792012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:26

Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:12:37
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:57:45
User entered '0'	Bettie Corcoran (b) (4)	25 Sep 2020 21:28:25

US3792012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:26

Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:12:37
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:57:45
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Bettie Corcoran (b) (4) (b) (4)	25 Sep 2020 21:28:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:12:37
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:57:45
User entered empty.	Bettie Corcoran (b) (4)	25 Sep 2020 21:28:25
	(b) (4)	

US3792012
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:48:26
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:12:37
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:57:45
User entered 'pt feels likely food borne illness'	Bettie Corcoran (b) (4) (b) (4)	25 Sep 2020 21:28:25

US3792012
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:48:26
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:12:37
User entered '0'	System	25 Sep 2020 21:28:25

US3792012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:26

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:12:37
User entered '0'	System	25 Sep 2020 21:28:25

US3792012

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:26

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:12:37

US3792012
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:48:26
AEID

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:51:05
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:22:37
User entered 'USA-US057-2021-mRNA-1273-P301000002'	System	25 Mar 2021 13:22:32
User entered 'New'	(b) (4), (b) (6)	25 Mar 2021 13:22:32

US3792012
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:48:26

Adverse event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:51:05
User closed query 'CRA cannot verify in source. Please update source.' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 17:48:20
Query 'CRA cannot verify in source. Please update source.' answered with 'source updated' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 15:48:42
User opened query 'CRA cannot verify in source. Please update source.' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 18:43:00
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Back pain aggravated - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Mar 2021 21:11:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Mar 2021 21:11:40
Data point term sent to Coder	System	24 Mar 2021 21:10:59
User entered 'Worsening of Chronic Back Pain'	(b) (4), (b) (6)	24 Mar 2021 21:10:54

US3792012

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:48:26

Was this a medically-attended AE?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:51:05
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Mar 2021 21:10:54

US3792012

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:48:26

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:51:05
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
User entered 'No (N)'	(b) (4), (b) (6)	24 Mar 2021 21:10:54

US3792012

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:48:26

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:51:05
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
User entered 'No (N)'	(b) (4), (b) (6)	24 Mar 2021 21:10:54

US3792012
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:48:26

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:11:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 21:12:02
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	09 Apr 2021 21:17:59
User entered '10 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 21:17:59
User closed query 'Source only states Jan2021 as start date, EDC states 01Jan. Please reconcile ' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 18:02:13
Query 'Source only states Jan2021 as start date, EDC states 01Jan. Please reconcile ' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 17:59:58
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	09 Apr 2021 17:59:11
User entered 'un Jan 2021' (non-conformant).	(b) (4), (b) (6)	09 Apr 2021 17:59:11
User opened query 'Source only states Jan2021 as start date, EDC states 01Jan. Please reconcile ' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 17:55:43
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 17:51:22
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:51:05
User closed query 'PV Query: Please confirm the event onset date as it is provided as 17 Feb 2021, but source narrative states "EXPERIENCED A WORSENING OF CHRONIC BACK PAIN IN JANUARY 2021."' (Site from Safety).	(b) (4), (b) (6)	05 Apr 2021 14:46:44
Query 'PV Query: Please confirm the event onset date as it is provided as 17 Feb 2021, but source narrative states "EXPERIENCED A WORSENING OF CHRONIC BACK PAIN IN JANUARY 2021."' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 21:52:27
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	02 Apr 2021 21:52:19
User entered '01 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Apr 2021 21:52:19
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	02 Apr 2021 21:50:47

PRODUCTION RELEASE (v12.003 EAB) (1725)

US3792012

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:48:26

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	02 Apr 2021 21:50:47
User entered ' Jan 2021' (non-conformant).	(b) (4), (b) (6)	02 Apr 2021 21:50:47
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	02 Apr 2021 21:49:53
Signature has been broken.	(b) (4), (b) (6)	02 Apr 2021 21:49:53
User entered 'un Jan 2021' (non-conformant).	(b) (4), (b) (6)	02 Apr 2021 21:49:53
User opened query 'PV Query: Please confirm the event onset date as it is provided as 17 Feb 2021, but source narrative states "EXPERIENCED A WORSENING OF CHRONIC BACK PAIN IN JANUARY 2021."' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 16:35:10
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
User entered '17 Feb 2021'	(b) (4), (b) (6)	24 Mar 2021 21:10:54

FDA-CBER-2022-1614-3382658

US3792012
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:48:26

Start time *(00:00-23:59)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:51:05
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
User entered empty.	(b) (4), (b) (6)	24 Mar 2021 21:10:54

US3792012

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:48:26

AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	24 Mar 2021 21:10:54

US3792012

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:48:26

Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:51:05
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:10:54

US3792012

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:48:26

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:14:53
User closed query 'PV Query: Event end date is reported as 17 Feb 2021 and hospital discharge date is provided as 19 Feb 2021. Please provide the reason why the subject remained hospitalized even after the event resolved. Did the subject experience another SAE?' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 16:36:47
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	19 Apr 2021 16:11:05
Query 'PV Query: Event end date is reported as 17 Feb 2021 and hospital discharge date is provided as 19 Feb 2021. Please provide the reason why the subject remained hospitalized even after the event resolved. Did the subject experience another SAE?' answered with 'updated' (Site from Safety).	Norma Frederick (b) (4) (b) (4)	16 Apr 2021 21:46:31
DataPoint Un-verified.	Norma Frederick (b) (4) (b) (4)	16 Apr 2021 21:46:14
User entered '19 Feb 2021' reason for change: Data Entry Error	Norma Frederick (b) (4) (b) (4)	16 Apr 2021 21:46:14
User opened query 'PV Query: Event end date is reported as 17 Feb 2021 and hospital discharge date is provided as 19 Feb 2021. Please provide the reason why the subject remained hospitalized even after the event resolved. Did the subject experience another SAE?' (Site from Safety).	(b) (4), (b) (6)	16 Apr 2021 13:26:23
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 21:12:02
User closed query 'Source states end date as 17Feb2021, EDC states 19Feb. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 21:11:43
Query 'Source states end date as 17Feb2021, EDC states 19Feb. Please reconcile.' answered with 'corrected error in entry' (Site from CRA).	Norma Frederick (b) (4) (b) (4)	09 Apr 2021 20:31:38
Signature has been broken.	Norma Frederick (b) (4) (b) (4)	09 Apr 2021 20:31:22
User entered '17 Feb 2021' reason for change: Data Entry Error	Norma Frederick (b) (4) (b) (4)	09 Apr 2021 20:31:22
User opened query 'Source states end date as 17Feb2021, EDC states 19Feb. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 17:52:32
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 17:51:34

US3792012

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:48:26

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:51:05
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
User entered '19 Feb 2021'	(b) (4), (b) (6)	24 Mar 2021 21:10:54

US3792012

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:48:26

End time *(00:00-23:59)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:51:05
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
User entered empty.	(b) (4), (b) (6)	24 Mar 2021 21:10:54

US3792012

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:48:26

AE End Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	24 Mar 2021 21:10:54

US3792012
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:48:26
Severity

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	19 Apr 2021 16:11:05
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:02:44
User closed query 'Per source severity is Grade 3. Please reconcile' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 18:02:28
Query 'Per source severity is Grade 3. Please reconcile' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 17:58:27
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 17:56:43
Signature has been broken.	(b) (4), (b) (6)	09 Apr 2021 17:56:43
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 17:56:43
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:51:05
User opened query 'Per source severity is Grade 3. Please reconcile' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 17:50:18
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Mar 2021 21:17:22
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Mar 2021 21:17:22
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Mar 2021 21:17:22
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Mar 2021 21:10:54
User entered empty.	(b) (4), (b) (6)	24 Mar 2021 21:10:54

US3792012
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:48:26
Is the adverse event serious?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:51:05
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	24 Mar 2021 21:11:35
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	24 Mar 2021 21:10:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Mar 2021 21:10:54

US3792012
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:48:26
Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:51:05
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
User entered '0'	(b) (4), (b) (6)	24 Mar 2021 21:10:54

US3792012

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:48:26

Life threatening

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:51:05
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	24 Mar 2021 21:10:54

US3792012
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:48:26
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:51:05
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
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	24 Mar 2021 21:11:35
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	24 Mar 2021 21:11:35
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Mar 2021 21:11:35
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	24 Mar 2021 21:10:54
User entered '0'	(b) (4), (b) (6)	24 Mar 2021 21:10:54

US3792012

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:48:26

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:51:05
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
User entered '17 Feb 2021'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:10:54

US3792012

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:48:26

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:51:05
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
User entered '19 Feb 2021'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:10:54

US3792012
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:48:26
Admitted to ICU?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:51:05
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
User entered 'No (N)'	(b) (4), (b) (6)	24 Mar 2021 21:10:54

US3792012

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:48:26

Number of Days in ICU

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:51:05
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:10:54

US3792012

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:48:26

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:51:05
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:10:54

US3792012

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:48:26

Congenital anomaly or birth defect

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:51:05
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:10:54

Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:48:26
Other medically important event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:51:05
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:10:54

US3792012
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:48:26
Relationship to investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:51:05
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:10:54

US3792012

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:48:26

Relationship to Study Procedure

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:51:05
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:10:54

US3792012

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:48:26

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:51:05
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:10:54

US3792012
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:48:26
None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:51:05
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	24 Mar 2021 21:17:49
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Mar 2021 21:17:49
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	24 Mar 2021 21:10:54
User entered '0'	(b) (4), (b) (6)	24 Mar 2021 21:10:54

US3792012

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:48:26

Concomitant Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:51:05
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
User entered '0'	(b) (4), (b) (6)	24 Mar 2021 21:10:54

US3792012
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:48:26
Concomitant Procedure

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:51:05
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
User entered '0'	(b) (4), (b) (6)	24 Mar 2021 21:10:54

US3792012
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:48:26
Outcome

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:51:05
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	24 Mar 2021 21:10:54

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:51:05
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:10:54

US3792012
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:48:26
Narrative

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 17:51:05
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so' (Site from Safety).	(b) (4), (b) (6)	07 Apr 2021 11:40:04
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	07 Apr 2021 11:40:01
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'No results available' (Site from Safety).	(b) (4), (b) (6)	06 Apr 2021 18:43:41
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so' answered with 'no results available' (Site from Safety).	(b) (4), (b) (6)	06 Apr 2021 18:43:02
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 16:35:36
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 16:35:27

FDA-CBER-2022-1614-3382686

US3792012

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:48:26

Narrative

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
User entered 'experienced a worsening of chronic back pain in January 2021. Evaluation performed by physician determined L4-L5 fusion recommended. Surgery, L4-L5 fusion performed on 17FEB2021. released from hospital on 19FEB2021.Patient informs they are recovered and released from Dr's care .'	(b) (4), (b) (6)	24 Mar 2021 21:10:54

US3792012

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:48:26

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '1'	System	24 Mar 2021 21:10:54

US3792012

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:48:26

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	24 Mar 2021 21:10:54

US3792012

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:48:26

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	24 Mar 2021 21:10:54

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:48:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:54:01
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:31
User entered 'Yes (Y)'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:46:38

FDA-CBER-2022-1614-3382691

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:48:26

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE SODIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 20:56:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 20:56:22
Data point term sent to Coder	System	20 Aug 2020 20:55:35
User entered 'levothyroxine sodium'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:55:34

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:48:26

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered 'No (N)'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:55:34

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:48:26

Indication

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered 'hypothyroidism'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:55:34

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:48:26

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered '25'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:55:34

FDA-CBER-2022-1614-3382695

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:48:26

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered 'ug (ug)'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:55:34

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:48:26

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:55:34

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:48:26

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered 'once daily (QD)'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:55:34

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:48:26

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:55:34

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:48:26

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered 'Oral (ORAL)'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:55:34

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:48:26

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:55:34

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:48:26

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 03:53:17
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ongoing' (Site from System).	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:57:34
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 20:55:34
User entered 'un UNK 2015'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:55:34

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:48:26

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered '0'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:55:34

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:48:26

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered 'Yes (Y)'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:55:34

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:48:26

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

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:55:34

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:48:26

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Aug 2020 20:57:41
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Aug 2020 20:57:41
User entered 'No (N)' reason for change: Data Entry Error	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:57:41
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Aug 2020 20:55:34
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:55:34

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:48:26

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 20:55:34

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:48:26

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 20:55:34

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:48:26

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Aug 2020 20:55:34

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:48:26

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
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 SODIUM SESQUIHYDRATE, PRODUCTSYNONYM: PANTOPRAZOLE SODIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 20:58:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 20:58:22
Data point term sent to Coder	System	20 Aug 2020 20:57:37
User entered 'pantoprazole sodium'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:57:03

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:48:26

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered 'No (N)'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:57:03

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:48:26

Indication

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered 'gastroesophageal reflux disease'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:57:03

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:48:26

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered '40'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:57:03

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:48:26

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered 'mg (mg)'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:57:03

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:48:26

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:57:03

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:48:26

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered 'once daily (QD)'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:57:03

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:48:26

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:57:03

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:48:26

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered 'Oral (ORAL)'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:57:03

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:48:26

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:57:03

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:48:26

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 03:53:17
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ongoing' (Site from System).	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:57:23
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 20:57:03
User entered 'un UNK 2017'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:57:03

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:48:26

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered '0'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:57:03

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:48:26

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered 'Yes (Y)'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:57:03

FDA-CBER-2022-1614-3382722

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:48:26

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

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:57:03

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:48:26

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered 'No (N)'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:57:03

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:48:26

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 20:57:03

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 20:57:03

FDA-CBER-2022-1614-3382726

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:48:26

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Aug 2020 20:57:03

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:48:26

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 21:00:26
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 21:00:26
Data point term sent to Coder	System	20 Aug 2020 20:59:41
User entered 'lisinopril'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:58:45

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:48:26

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered 'No (N)'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:58:45

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:48:26

Indication

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered 'hypertension'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:58:45

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:48:26

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered '10'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:58:45

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:48:26

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered 'mg (mg)'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:58:45

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:48:26

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:58:45

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:48:26

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered 'once daily (QD)'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:58:45

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:48:26

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:58:45

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:48:26

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered 'Oral (ORAL)'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:58:45

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:48:26

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:58:45

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:48:26

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 03:53:17
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ongoing' (Site from System).	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:58:52
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 20:58:45
User entered 'un UNK 2015'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:58:45

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:48:26

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered '0'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:58:45

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:48:26

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered 'Yes (Y)'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:58:45

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:48:26

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

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:58:45

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:48:26

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered 'No (N)'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 20:58:45

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:48:26

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 20:58:45

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:48:26

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 20:58:45

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:48:26

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Aug 2020 20:58:45

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:48:26

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS, PRODUCT: VALACICLOVIR HYDROCHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 07:25:12
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 07:25:12
Data point term sent to Coder	System	20 Aug 2020 21:00:42
User entered 'valcyclovir hcl'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 21:00:21

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:48:26

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered 'No (N)'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 21:00:21

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:48:26

Indication

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered 'herpes symplex type I'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 21:00:21

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:48:26

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered '500'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 21:00:21

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:48:26

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered 'mg (mg)'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 21:00:21

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:48:26

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 21:00:21

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:48:26

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered 'once daily (QD)'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 21:00:21

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:48:26

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 21:00:21

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:48:26

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered 'Oral (ORAL)'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 21:00:21

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:48:26

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 21:00:21

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:48:26

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 03:53:17
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ongoing' (Site from System).	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 21:00:35
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 21:00:21
User entered 'un UNK 2018'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 21:00:21

FDA-CBER-2022-1614-3382756

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:48:26

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered '0'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 21:00:21

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:48:26

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered 'Yes (Y)'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 21:00:21

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:48:26

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

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 21:00:21

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:48:26

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered 'No (N)'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 21:00:21

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:48:26

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 21:00:21

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:48:26

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 21:00:21

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:48:26

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Aug 2020 21:00:21

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:48:26

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 21:06:56
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTI-DEMENTIA DRUGS, ATC: OTHER ANTI-DEMENTIA DRUGS, PRODUCT: APOAEQUORIN, PRODUCTSYNONYM: PREVAGEN [APOAEQUORIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 07:43:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 07:43:45
Data point term sent to Coder	System	20 Aug 2020 21:03:47
User entered 'prevagen apoaequorin total carbohydrate'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 21:03:23

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:48:26

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered 'No (N)'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 21:03:23

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:48:26

Indication

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered 'nutritional supplement'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 21:03:23

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:48:26

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered '1'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 21:03:23

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:48:26

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered 'tablet (TABLET)'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 21:03:23

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:48:26

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 21:03:23

FDA-CBER-2022-1614-3382769

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:48:26

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered 'once daily (QD)'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 21:03:23

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:48:26

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 21:03:23

FDA-CBER-2022-1614-3382771

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:48:26

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered 'Oral (ORAL)'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 21:03:23

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:48:26

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 21:03:23

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:48:26

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 03:53:17
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ongoing' (Site from System).	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 21:03:30
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 21:03:23
User entered 'un UNK 2017'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 21:03:23

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:48:26

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered '0'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 21:03:23

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:48:26

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered 'Yes (Y)'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 21:03:23

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:48:26

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

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 21:03:23

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:48:26

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered 'No (N)'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 21:03:23

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:48:26

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 21:03:23

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:48:26

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 21:03:23

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:48:26

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Aug 2020 21:03:23

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:48:26

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), PLAIN, PRODUCT: ASCORBIC ACID, PRODUCTSYNONYM: VITAMIN C [ASCORBIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 21:05:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 21:05:27
Data point term sent to Coder	System	20 Aug 2020 21:04:53
User entered 'vitamin c'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 21:04:29

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:48:26

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered 'No (N)'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 21:04:29

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:48:26

Indication

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered 'nutritional supplement'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 21:04:29

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:48:26

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered '500'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 21:04:29

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:48:26

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered 'mg (mg)'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 21:04:29

FDA-CBER-2022-1614-3382786

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:48:26

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 21:04:29

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:48:26

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered 'once daily (QD)'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 21:04:29

FDA-CBER-2022-1614-3382788

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:48:26

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 21:04:29

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:48:26

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered 'Oral (ORAL)'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 21:04:29

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:48:26

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 21:04:29

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:48:26

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 03:53:17
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ongoing' (Site from System).	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 21:04:38
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 21:04:29
User entered 'un UNK 2017'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 21:04:29

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:48:26

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered '0'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 21:04:29

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:48:26

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered 'Yes (Y)'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 21:04:29

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:48:26

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

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 21:04:29

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:48:26

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered 'No (N)'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 21:04:29

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:48:26

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 21:04:29

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:48:26

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 21:04:29

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:48:26

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Aug 2020 21:04:29

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:48:26

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 21:08:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 21:08:29
Data point term sent to Coder	System	20 Aug 2020 21:06:55
User entered 'multivitamin'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 21:06:00

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:48:26

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered 'No (N)'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 21:06:00

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:48:26

Indication

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered 'nutritional supplement'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 21:06:00

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:48:26

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered '1'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 21:06:00

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:48:26

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered 'tablet (TABLET)'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 21:06:00

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:48:26

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 21:06:00

FDA-CBER-2022-1614-3382805

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:48:26

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered 'once daily (QD)'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 21:06:00

FDA-CBER-2022-1614-3382806

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:48:26

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 21:06:00

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:48:26

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered 'Oral (ORAL)'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 21:06:00

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:48:26

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 21:06:00

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:48:26

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 03:53:17
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ongoing' (Site from System).	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 21:07:00
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 21:06:42
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	20 Aug 2020 21:06:42
User entered 'UN UNK 2000' reason for change: Data Entry Error	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 21:06:42
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	20 Aug 2020 21:06:00
User entered 'un ' (non-conformant).	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 21:06:00

FDA-CBER-2022-1614-3382810

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:48:26

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered '0'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 21:06:00

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:48:26

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered 'Yes (Y)'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 21:06:00

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:48:26

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

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 21:06:00

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:48:26

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered 'No (N)'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 21:06:00

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:48:26

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 21:06:00

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:48:26

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 21:06:00

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:48:26

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Aug 2020 21:06:00

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:48:26

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: ANTIINFLAMMATORY PREPARATIONS, NON-STEROIDS FOR TOPICAL USE, PRODUCT: DICLOFENAC, PRODUCTSYNONYM: VOLTAREN [DICLOFENAC] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 07:06:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 07:06:16
Data point term sent to Coder	System	20 Aug 2020 21:10:02
User entered 'voltaren'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 21:09:18

FDA-CBER-2022-1614-3382818

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:48:26

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered 'No (N)'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 21:09:18

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:48:26

Indication

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered 'left hand pain'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 21:09:18

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:48:26

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered '1'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 21:09:18

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:48:26

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered 'Other (OTHER)'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 21:09:18

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:48:26

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered 'application'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 21:09:18

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:48:26

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered 'as needed (PRN)'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 21:09:18

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:48:26

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 21:09:18

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:48:26

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered 'Topical (TOPICAL)'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 21:09:18

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:48:26

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 21:09:18

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:48:26

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 03:53:17
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ongoing' (Site from System).	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 21:09:27
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 21:09:18
User entered 'un UNK 2018'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 21:09:18

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:48:26

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered '0'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 21:09:18

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:48:26

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered 'Yes (Y)'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 21:09:18

FDA-CBER-2022-1614-3382830

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:48:26

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

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 21:09:18

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:48:26

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 16:08:17
DataPoint Un-verified.	(b) (4), (b) (6)	11 Sep 2020 21:12:02
DataPoint Verified.	(b) (4), (b) (6)	11 Sep 2020 21:06:56
User entered 'No (N)'	Scarlett Hammett (b) (4) (b) (4)	20 Aug 2020 21:09:18

FDA-CBER-2022-1614-3382832

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:48:26

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 21:09:18

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:48:26

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 21:09:18

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:48:26

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 21:09:18

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:48:26

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:33:07
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 17:23:55
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 18:58:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Nov 2020 18:58:47
Data point term sent to Coder	System	18 Nov 2020 18:57:23
User entered 'FLU VACCINE'	Scarlett Hammett (b) (4) (b) (4)	18 Nov 2020 18:56:40

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:48:26

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:33:07
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 17:23:55
User entered 'Yes (Y)'	Scarlett Hammett (b) (4) (b) (4)	18 Nov 2020 18:56:40

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:48:26

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:33:07
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 17:23:55
User entered 'FLU PROPHYLAXIS'	Scarlett Hammett (b) (4) (b) (4)	18 Nov 2020 18:56:40

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:48:26

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:33:07
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 17:23:55
User entered '1'	Scarlett Hammett (b) (4) (b) (4)	18 Nov 2020 18:56:40

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:48:26

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:33:07
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 17:23:55
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Nov 2020 19:00:50
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Nov 2020 19:00:50
User entered 'Other (OTHER)' reason for change: Data Entry Error	Scarlett Hammett (b) (4) (b) (4)	18 Nov 2020 19:00:50
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Nov 2020 18:56:40
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	18 Nov 2020 18:56:40

FDA-CBER-2022-1614-3382840

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:48:26

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:33:07
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 17:23:55
User entered 'INJECTION'	Scarlett Hammett (b) (4) (b) (4)	18 Nov 2020 18:56:40

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:48:26

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:33:07
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 17:23:55
User closed query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	18 Nov 2020 19:00:50
Query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' answered by data change (Site from System).	System	18 Nov 2020 19:00:50
User opened query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	18 Nov 2020 18:56:40
User entered 'once (ONCE)'	Scarlett Hammett (b) (4) (b) (4)	18 Nov 2020 18:56:40

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:48:26

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:33:07
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 17:23:55
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	18 Nov 2020 18:56:40

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:48:26

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:33:07
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 17:23:55
User entered 'Intramuscular (INTRAMUSCULAR)'	Scarlett Hammett (b) (4) (b) (4)	18 Nov 2020 18:56:40

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:48:26

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:33:07
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 17:23:55
User entered empty.	Scarlett Hammett (b) (4) (b) (4)	18 Nov 2020 18:56:40

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:48:26

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:33:07
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 17:23:55
User entered '25 Sep 2020'	Scarlett Hammett (b) (4)	18 Nov 2020 18:56:40

FDA-CBER-2022-1614-3382846

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:48:26

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:33:07
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 17:23:55
User entered '0'	Scarlett Hammett (b) (4) (b) (4)	18 Nov 2020 18:56:40

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:48:26

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:33:07
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 17:23:55
User entered 'No (N)'	Scarlett Hammett (b) (4)	18 Nov 2020 18:56:40

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:48:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:33:07
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 17:23:55
User entered '25 Sep 2020' reason for change: Data Entry Error	Scarlett Hammett (b) (4) (b) (4)	18 Nov 2020 19:00:50
User entered '25 Oct 2020'	Scarlett Hammett (b) (4) (b) (4)	18 Nov 2020 18:56:40

FDA-CBER-2022-1614-3382849

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:48:26

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:33:07
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 17:23:55
User entered 'No (N)'	Scarlett Hammett (b) (4) (b) (4)	18 Nov 2020 18:56:40

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:48:26

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:33:07
User entered empty.	System	18 Nov 2020 18:56:40

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:48:26

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:33:07
User entered empty.	System	18 Nov 2020 18:56:40

US3792012

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:48:26

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:33:07
User entered empty.	System	18 Nov 2020 18:56:40

US3792012

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:48:26

Were any concomitant procedures performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:54:01
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 18:07:53
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Mar 2021 20:54:03
User entered 'No (N)'	Scarlett Hammett (b) (4) (b) (4)	13 Feb 2021 00:51:28

US3792012

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:48:26

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:08:49
User closed query 'CRA cannot verify in source. Please update source.' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 18:08:30
Query 'CRA cannot verify in source. Please update source.' answered with 'misfiled, binder updated' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 23:03:07
User opened query 'CRA cannot verify in source. Please update source.' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 18:44:27
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
User entered '17 Feb 2021'	(b) (4), (b) (6)	24 Mar 2021 20:54:50

US3792012

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:48:26

Procedure/Surgery

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:08:49
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
User entered 'L4-L5 fusion'	(b) (4), (b) (6)	24 Mar 2021 20:54:50

US3792012

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:48:26

Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:08:49
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
User entered 'Medical History (MH)'	(b) (4), (b) (6)	24 Mar 2021 20:54:50

US3792012

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:48:26

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 18:08:49
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:54:50

US3792012
Folder: SAE USA-US057-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 09:48:26
SAEID

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:27:03
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:22:59
User entered 'USA-US057-2021-MRNA-1273-P301000002'	System	25 Mar 2021 13:22:32

US3792012
Folder: SAE USA-US057-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 09:48:26
Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:27:03
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:22:59
User entered 'Yes (Y)'	System	25 Mar 2021 13:22:32

US3792012
Folder: SAE USA-US057-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 09:48:26

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:27:03
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:22:59
User entered 'No (N)'	System	25 Mar 2021 13:22:32

US3792012
Folder: SAE USA-US057-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 09:48:26
Life threatening

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:27:03
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:22:59
User entered 'No (N)'	System	25 Mar 2021 13:22:32

US3792012
Folder: SAE USA-US057-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 09:48:26
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:27:03
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:22:59
User entered 'Yes (Y)'	System	25 Mar 2021 13:22:32

US3792012

Folder: SAE USA-US057-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:26

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:27:03
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:22:59
User entered 'No (N)'	System	25 Mar 2021 13:22:32

US3792012
Folder: SAE USA-US057-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 09:48:26
Congenital anomaly or birth defect

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:27:03
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:22:59
User entered 'No (N)'	System	25 Mar 2021 13:22:32

FDA-CBER-2022-1614-3382865

US3792012
Folder: SAE USA-US057-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 09:48:26
Other medically important event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:27:03
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:22:59
User entered 'No (N)'	System	25 Mar 2021 13:22:32

US3792012
Folder: SAE USA-US057-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 09:48:26
Investigator's First Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:27:03
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:22:59
User entered 'Abram'	System	25 Mar 2021 13:22:32

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:27:03
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:22:59
User entered 'Burgher'	System	25 Mar 2021 13:22:32

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:27:03
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:22:59
User entered '3900 East Camelback Road'	System	25 Mar 2021 13:22:32

US3792012
Folder: SAE USA-US057-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 09:48:26

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:27:03
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:22:59
User entered 'Phoenix'	System	25 Mar 2021 13:22:32

US3792012
Folder: SAE USA-US057-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 09:48:26
Site Address: State

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 16:37:29
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	19 Apr 2021 16:11:05
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:56:40
User entered empty.	Norma Frederick (b) (4) (b) (4)	16 Apr 2021 21:52:32

US3792012
Folder: SAE USA-US057-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 09:48:26
Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:27:03
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:22:59
User entered '85018'	System	25 Mar 2021 13:22:32

US3792012
Folder: SAE USA-US057-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 09:48:26
Investigator Country

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:27:03
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 14:47:11
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
User entered 'US'	System	25 Mar 2021 13:23:06

US3792012
Folder: SAE USA-US057-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 09:48:26
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '4'	System	19 Apr 2021 16:37:55
User entered '3'	System	12 Apr 2021 16:15:48
User entered '2'	System	05 Apr 2021 14:47:08
User entered '1'	System	25 Mar 2021 13:23:06

US3792012
Folder: SAE USA-US057-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 09:48:26
SAEID

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:27:03
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:22:59
User entered 'USA-US057-2021-MRNA-1273-P301000002'	System	25 Mar 2021 13:22:32

US3792012
Folder: SAE USA-US057-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 09:48:26
Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:27:03
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:22:59
User entered 'Yes (Y)'	System	25 Mar 2021 13:22:32

US3792012
Folder: SAE USA-US057-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 09:48:26
Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:27:03
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:22:59
User entered 'No (N)'	System	25 Mar 2021 13:22:32

US3792012
Folder: SAE USA-US057-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 09:48:26
Life threatening

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:27:03
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:22:59
User entered 'No (N)'	System	25 Mar 2021 13:22:32

US3792012
Folder: SAE USA-US057-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 09:48:26

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:27:03
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:22:59
User entered 'Yes (Y)'	System	25 Mar 2021 13:22:32

US3792012
Folder: SAE USA-US057-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 09:48:26
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:27:03
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:22:59
User entered 'No (N)'	System	25 Mar 2021 13:22:32

US3792012
Folder: SAE USA-US057-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 09:48:26
Congenital anomaly or birth defect

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:27:03
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:22:59
User entered 'No (N)'	System	25 Mar 2021 13:22:32

US3792012
Folder: SAE USA-US057-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 09:48:26
Other medically important event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:27:03
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:22:59
User entered 'No (N)'	System	25 Mar 2021 13:22:32

US3792012
Folder: SAE USA-US057-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 09:48:26
Investigator's First Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:27:03
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:22:59
User entered 'Abram'	System	25 Mar 2021 13:22:32

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:27:03
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:22:59
User entered 'Burgher'	System	25 Mar 2021 13:22:32

US3792012
Folder: SAE USA-US057-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 09:48:26
Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:27:03
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:22:59
User entered '3900 East Camelback Road'	System	25 Mar 2021 13:22:32

FDA-CBER-2022-1614-3382885

US3792012
Folder: SAE USA-US057-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 09:48:26
Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:27:03
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:22:59
User entered 'Phoenix'	System	25 Mar 2021 13:22:32

US3792012
Folder: SAE USA-US057-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 09:48:26
Site Address: State

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 16:37:29
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:11:05
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:56:40
User entered empty.	Norma Frederick (b) (4) (b) (4)	16 Apr 2021 21:52:32

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:27:03
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:22:59
User entered '85018'	System	25 Mar 2021 13:22:32

US3792012
Folder: SAE USA-US057-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 09:48:26

Investigator Country

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:27:03
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 14:47:11
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
User entered 'US'	System	25 Mar 2021 13:23:06

US3792012
Folder: SAE USA-US057-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 09:48:26
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '4'	System	19 Apr 2021 16:37:55
User entered '3'	System	12 Apr 2021 16:15:48
User entered '2'	System	05 Apr 2021 14:47:08
User entered '1'	System	25 Mar 2021 13:23:06

US3792012
Folder: SAE USA-US057-2021-MRNA-1273-P301000002
Form: Safety Report Form (1)
Generated On: 10 Jun 2021 09:48:26
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:27:03
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
User entered '25/Mar/2021 13:23'	System	25 Mar 2021 13:23:06

US3792012

Folder: SAE USA-US057-2021-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:48:26

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:27:03
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 14:47:11
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
User entered '1'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:23:06

US3792012
Folder: SAE USA-US057-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 09:48:26
SAEID

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:27:03
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:22:59
User entered 'USA-US057-2021-MRNA-1273-P301000002'	System	25 Mar 2021 13:22:32

US3792012
Folder: SAE USA-US057-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 09:48:26
Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:27:03
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:22:59
User entered 'Yes (Y)'	System	25 Mar 2021 13:22:32

US3792012
Folder: SAE USA-US057-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 09:48:26
Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:27:03
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:22:59
User entered 'No (N)'	System	25 Mar 2021 13:22:32

Life threatening

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:27:03
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:22:59
User entered 'No (N)'	System	25 Mar 2021 13:22:32

FDA-CBER-2022-1614-3382896

US3792012
Folder: SAE USA-US057-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 09:48:26
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:27:03
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:22:59
User entered 'Yes (Y)'	System	25 Mar 2021 13:22:32

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:27:03
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:22:59
User entered 'No (N)'	System	25 Mar 2021 13:22:32

US3792012
Folder: SAE USA-US057-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 09:48:26
Congenital anomaly or birth defect

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:27:03
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:22:59
User entered 'No (N)'	System	25 Mar 2021 13:22:32

US3792012
Folder: SAE USA-US057-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 09:48:26
Other medically important event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:27:03
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:22:59
User entered 'No (N)'	System	25 Mar 2021 13:22:32

US3792012
Folder: SAE USA-US057-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 09:48:26
Investigator's First Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:27:03
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:22:59
User entered 'Abram'	System	25 Mar 2021 13:22:32

US3792012
Folder: SAE USA-US057-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 09:48:26
Investigator's Last Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:27:03
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:22:59
User entered 'Burgher'	System	25 Mar 2021 13:22:32

US3792012
Folder: SAE USA-US057-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 09:48:26
Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:27:03
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:22:59
User entered '3900 East Camelback Road'	System	25 Mar 2021 13:22:32

US3792012
Folder: SAE USA-US057-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 09:48:26
Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:27:03
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:22:59
User entered 'Phoenix'	System	25 Mar 2021 13:22:32

US3792012
Folder: SAE USA-US057-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 09:48:26
Site Address: State

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 16:37:29
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:11:05
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:56:40
User entered empty.	Norma Frederick (b) (4)	16 Apr 2021 21:52:32

US3792012
Folder: SAE USA-US057-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 09:48:26
Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:27:03
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:22:59
User entered '85018'	System	25 Mar 2021 13:22:32

US3792012
Folder: SAE USA-US057-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 09:48:26
Investigator Country

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:27:03
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 14:47:11
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
User entered 'US'	System	25 Mar 2021 13:23:06

US3792012
Folder: SAE USA-US057-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 09:48:26
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '4'	System	19 Apr 2021 16:37:55
User entered '3'	System	12 Apr 2021 16:15:48
User entered '2'	System	05 Apr 2021 14:47:08
User entered '1'	System	25 Mar 2021 13:23:06

US3792012

Folder: SAE USA-US057-2021-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:48:26

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:27:03
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	08 Apr 2021 22:49:29
User entered '05/Apr/2021 10:47'	System	05 Apr 2021 14:47:08

US3792012

Folder: SAE USA-US057-2021-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:48:26

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:27:03
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	08 Apr 2021 22:49:29
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 14:47:11
User entered '1'	(b) (4), (b) (6)	05 Apr 2021 14:47:08

US3792012
Folder: SAE USA-US057-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 09:48:26
SAEID

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:27:03
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:22:59
User entered 'USA-US057-2021-MRNA-1273-P301000002'	System	25 Mar 2021 13:22:32

US3792012
Folder: SAE USA-US057-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 09:48:26
Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:27:03
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:22:59
User entered 'Yes (Y)'	System	25 Mar 2021 13:22:32

US3792012
Folder: SAE USA-US057-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 09:48:26
Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:27:03
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:22:59
User entered 'No (N)'	System	25 Mar 2021 13:22:32

US3792012
Folder: SAE USA-US057-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 09:48:26
Life threatening

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:27:03
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:22:59
User entered 'No (N)'	System	25 Mar 2021 13:22:32

US3792012
Folder: SAE USA-US057-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 09:48:26
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:27:03
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:22:59
User entered 'Yes (Y)'	System	25 Mar 2021 13:22:32

US3792012

Folder: SAE USA-US057-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:26

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:27:03
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:22:59
User entered 'No (N)'	System	25 Mar 2021 13:22:32

US3792012
Folder: SAE USA-US057-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 09:48:26
Congenital anomaly or birth defect

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:27:03
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:22:59
User entered 'No (N)'	System	25 Mar 2021 13:22:32

FDA-CBER-2022-1614-3382917

US3792012
Folder: SAE USA-US057-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 09:48:26
Other medically important event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:27:03
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:22:59
User entered 'No (N)'	System	25 Mar 2021 13:22:32

US3792012
Folder: SAE USA-US057-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 09:48:26
Investigator's First Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:27:03
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:22:59
User entered 'Abram'	System	25 Mar 2021 13:22:32

US3792012
Folder: SAE USA-US057-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 09:48:26
Investigator's Last Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:27:03
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:22:59
User entered 'Burgher'	System	25 Mar 2021 13:22:32

US3792012
Folder: SAE USA-US057-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 09:48:26
Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:27:03
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:22:59
User entered '3900 East Camelback Road'	System	25 Mar 2021 13:22:32

US3792012
Folder: SAE USA-US057-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 09:48:26
Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:27:03
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:22:59
User entered 'Phoenix'	System	25 Mar 2021 13:22:32

US3792012
Folder: SAE USA-US057-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 09:48:26

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 16:37:29
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:11:05
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:56:40
User entered empty.	Norma Frederick (b) (4)	16 Apr 2021 21:52:32

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:27:03
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:22:59
User entered '85018'	System	25 Mar 2021 13:22:32

US3792012
Folder: SAE USA-US057-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 09:48:26

Investigator Country

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:27:03
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 14:47:11
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
User entered 'US'	System	25 Mar 2021 13:23:06

US3792012
Folder: SAE USA-US057-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 09:48:26
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '4'	System	19 Apr 2021 16:37:55
User entered '3'	System	12 Apr 2021 16:15:48
User entered '2'	System	05 Apr 2021 14:47:08
User entered '1'	System	25 Mar 2021 13:23:06

US3792012
Folder: SAE USA-US057-2021-MRNA-1273-P301000002
Form: Safety Report Form (3)
Generated On: 10 Jun 2021 09:48:26
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:11:05
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:56:40
User entered '12/Apr/2021 11:15'	System	12 Apr 2021 16:15:48

US3792012

Folder: SAE USA-US057-2021-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:48:26

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 16:37:29
User signature succeeded.	Abram Burgher (b) (4)	19 Apr 2021 16:11:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:56:40
User entered '1'	(b) (4), (b) (6)	12 Apr 2021 16:15:48

US3792012
Folder: SAE USA-US057-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 09:48:26
SAEID

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:27:03
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:22:59
User entered 'USA-US057-2021-MRNA-1273-P301000002'	System	25 Mar 2021 13:22:32

US3792012
Folder: SAE USA-US057-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 09:48:26
Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:27:03
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:22:59
User entered 'Yes (Y)'	System	25 Mar 2021 13:22:32

US3792012
Folder: SAE USA-US057-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 09:48:26
Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:27:03
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:22:59
User entered 'No (N)'	System	25 Mar 2021 13:22:32

US3792012
Folder: SAE USA-US057-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 09:48:26
Life threatening

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:27:03
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:22:59
User entered 'No (N)'	System	25 Mar 2021 13:22:32

US3792012
Folder: SAE USA-US057-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 09:48:26
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:27:03
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:22:59
User entered 'Yes (Y)'	System	25 Mar 2021 13:22:32

Folder: SAE USA-US057-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 09:48:26
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:27:03
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:22:59
User entered 'No (N)'	System	25 Mar 2021 13:22:32

US3792012
Folder: SAE USA-US057-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 09:48:26
Congenital anomaly or birth defect

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:27:03
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:22:59
User entered 'No (N)'	System	25 Mar 2021 13:22:32

US3792012
Folder: SAE USA-US057-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 09:48:26
Other medically important event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:27:03
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:22:59
User entered 'No (N)'	System	25 Mar 2021 13:22:32

FDA-CBER-2022-1614-3382936

US3792012
Folder: SAE USA-US057-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 09:48:26
Investigator's First Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:27:03
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:22:59
User entered 'Abram'	System	25 Mar 2021 13:22:32

FDA-CBER-2022-1614-3382937

US3792012
Folder: SAE USA-US057-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 09:48:26
Investigator's Last Name

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:27:03
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:22:59
User entered 'Burgher'	System	25 Mar 2021 13:22:32

US3792012
Folder: SAE USA-US057-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 09:48:26
Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:27:03
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:22:59
User entered '3900 East Camelback Road'	System	25 Mar 2021 13:22:32

US3792012
Folder: SAE USA-US057-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 09:48:26

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:27:03
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:22:59
User entered 'Phoenix'	System	25 Mar 2021 13:22:32

US3792012
Folder: SAE USA-US057-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 09:48:26
Site Address: State

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 16:37:29
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	19 Apr 2021 16:11:05
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:56:40
User entered empty.	Norma Frederick (b) (4) (b) (4)	16 Apr 2021 21:52:32

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:27:03
User signature succeeded.	Abram Burgher (b) (4)	01 Apr 2021 20:40:19
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:22:59
User entered '85018'	System	25 Mar 2021 13:22:32

US3792012
Folder: SAE USA-US057-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 09:48:26
Investigator Country

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:27:03
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 14:47:11
User signature succeeded.	Abram Burgher (b) (4) (b) (4)	01 Apr 2021 20:40:19
User entered 'US'	System	25 Mar 2021 13:23:06

US3792012
Folder: SAE USA-US057-2021-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 10 Jun 2021 09:48:26
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '4'	System	19 Apr 2021 16:37:55
User entered '3'	System	12 Apr 2021 16:15:48
User entered '2'	System	05 Apr 2021 14:47:08
User entered '1'	System	25 Mar 2021 13:23:06

US3792012
Folder: SAE USA-US057-2021-MRNA-1273-P301000002
Form: Safety Report Form (4)
Generated On: 10 Jun 2021 09:48:26
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Abram Burgher (b) (4)	28 Apr 2021 05:39:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:15:05
User entered '19/Apr/2021 12:37'	System	19 Apr 2021 16:37:55

US3792012

Folder: SAE USA-US057-2021-MRNA-1273-P301000002

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:48:26

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.	Abram Burgher (b) (4)	28 Apr 2021 05:39:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:15:05
User entered '1'	(b) (4), (b) (6)	19 Apr 2021 16:37:55