US3522082 (Prod: Henry Ford Health System)

All time stamps listed in this document are displayed in GMT

US3522082

Form: Participant Creation

Data signed: (b) (4) **21 Feb 2021 21:20:17**

Generated On: 10 Jun 2021 08:00:15

Participant ID US3522082

mRNA-1273-P301 Completion Guidelines

US3522082

Folder: Screening

Form: Visit Date

Data signed: [(b) (4)] **21 Feb 2021 21:20:17**

Generated On: 10 Jun 2021 08:00:15

Was this visit performed?	Yes ●
	No ◯

Visit date (dd MMM yyyy)	11 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ◯
	Clinic ●

Folder OID	SCRN

US3522082

Folder: Screening

Form: Demographics

Data signed: (b) (4) **21 Feb 2021 21:20:17**

Generated On: 10 Jun 2021 08:00:15

Date of Birth (MMM yyyy)	(b) (6) 1957
Age	62
Age Units	YEARS
Age (Derived)	62
Sex	Female ◯
	Male ⬤
Ethnicity	Hispanic or Latino ◯
	Not Hispanic or Latino ⬤
	Not Reported ◯
	Unknown ◯

Race (Check All That Apply)

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

US3522082

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 21 Feb 2021 21:20:17

Generated On: 10 Jun 2021 08:00:15

Date of Informed Consent *(dd MMM yyyy)*	11 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

US3522082

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) **21 Feb 2021 21:20:17**

Generated On: 10 Jun 2021 08:00:15

Did the participant meet all eligibility criteria?   Yes ⬤

                                                                                          No ◯

Folder: Screening
Form: Medical History Summary
Data signed: (b) (4) **21 Feb 2021 21:20:17**
Generated On: 10 Jun 2021 08:00:15

Were any significant conditions reported?   Yes ●
                                             No ◯

US3522082

Folder: Screening

Form: Medical History (1)

Data signed: [(b) (4)] **12 Apr 2021 11:52:25**

Generated On: 10 Jun 2021 08:00:15

Condition	CORONARY ARTERY DISEASE
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

US3522082

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) **12 Apr 2021 11:52:25**

Generated On: 10 Jun 2021 08:00:15

Condition	ICD IMPLANT
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

US3522082

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) **12 Apr 2021 11:52:25**

Generated On: 10 Jun 2021 08:00:15

Condition	PRIMARY HYPERTENSION
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) **12 Apr 2021 11:52:25**

Generated On: 10 Jun 2021 08:00:15

Condition	IRON DEFICIENCY ANEMIA
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

US3522082

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) **12 Apr 2021 11:52:25**

Generated On: 10 Jun 2021 08:00:15

Condition	GERD
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

US3522082

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) **21 Feb 2021 21:20:28**

Generated On: 10 Jun 2021 08:00:15

Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	11 AUG 2020
Time of assessment *(00:00-23:59)*	13:30 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 13:30
Height *(xxx.x)*	66.5 in
Weight *(xxx.x)*	155.7 lb
BMI *(xxx.x)*	24.80591 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)	

US3522082

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) **21 Feb 2021 21:20:17**

Generated On: 10 Jun 2021 08:00:15

Was the physical examination performed?   Yes ●

                                                                          No ○

Date of examination *(dd MMM yyyy)*   11 AUG 2020

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

US3522082

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) **21 Feb 2021 21:20:17**

Generated On: 10 Jun 2021 08:00:15

Occupational Risk

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

Specify _____

Location and Living Circumstances Risk (check all that apply)

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

Folder: Screening
Form: Risk of Exposure
Data signed: (b) (4) **21 Feb 2021 21:20:17**
Generated On: 10 Jun 2021 08:00:15

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

US3522082

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) **16 Feb 2021 17:06:52**

Generated On: 10 Jun 2021 08:00:15

Was this visit performed?	Yes ⬤
	No ◯

Visit date (dd MMM yyyy)	11 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ◯
	Clinic ⬤

Folder OID	VISIT1

US3522082

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) **16 Feb 2021 17:06:52**

Generated On: 10 Jun 2021 08:00:15

What was the date of randomization? *(dd MMM yyyy)*	11 AUG 2020
What was the participant's randomization number?	103004

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 ●

US3522082

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) **16 Feb 2021 17:06:52**

Generated On: 10 Jun 2021 08:00:15

Height	ND - Not Done
Weight	ND - Not Done

US3522082

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4)   **16 Feb 2021 17:06:52**

Generated On: 10 Jun 2021 08:00:15

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)*	11 AUG 2020
Time of assessment *(00:00-23:59)*	13:30 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 13:30
Temperature *(xxx.x)*	96.4 F
Route of measurement	Oral ◯
	Axillary ◯
	Other ⬤
If Other, specify	TEMPORAL
Pulse *(xxx)*	70 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	98 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	67 mmHg
Diastolic Blood Pressure units	MMHG

US3522082

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) **16 Feb 2021 17:06:52**

Generated On: 10 Jun 2021 08:00:15

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)*	11 AUG 2020
Time of assessment *(00:00-23:59)*	15:25 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 15:25
Temperature *(xxx.x)*	97.4 F
Route of measurement	Oral ⬭
	Axillary ⬭
	Other ⬤
If Other, specify	TEMPORAL
Pulse *(xxx)*	65 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	111 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	70 mmHg
Diastolic Blood Pressure units	MMHG

US3522082

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) **16 Feb 2021 17:06:52**

Generated On: 10 Jun 2021 08:00:15

Was the physical examination performed?   Yes ◯

No ⬤

Date of examination *(dd MMM yyyy)* _____

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

| Was 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)*	11 AUG 2020
What was the treatment time? *(00:00-23:59)*	14:57 (24 HR)
Treatment Date and Time (derived)	11 AUG 2020 14:57
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-2022-1614-0811347

US3522082

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: ▨ (b) (4) ▨ **16 Feb 2021 17:06:52**

Generated On: 10 Jun 2021 08:00:15

Was the sample collected?	Yes ●
	No ○
Collection date *(dd MMM yyyy)*	11 AUG 2020
Collection time *(00:00-23:59)*	14:15 (24 HR)
Collection date and time (derived)	11 AUG 2020 14:15

US3522082

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) **16 Feb 2021 17:06:52**

Generated On: 10 Jun 2021 08:00:15

Collection date *(dd MMM yyyy)*			11 AUG 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:17	11 AUG 2020 14:17
Nasopharyngeal Swab 2	No		

US3522082

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) **16 Feb 2021 17:06:52**

Generated On: 10 Jun 2021 08:00:15

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**	97.4 °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	11 AUG 2020 15:19
PC Open Date & Time	11 AUG 2020 15:17
PC Close Date & Time	11 AUG 2020 17:47

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**	97.3 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

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

PC Time Stamp	11 AUG 2020 18:51
PC Open Date & Time	11 AUG 2020 18:42
PC Close Date & Time	12 AUG 2020 11:59

US3522082

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:00:15

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**	96.3 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	12 AUG 2020 12:03
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3522082

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:00:15

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**	97.3 °F

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

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

PC Time Stamp	13 AUG 2020 12:15
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3522082
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 08:00:15

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**	97.3 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	14 AUG 2020 17:27
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

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**	95.9 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

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

PC Time Stamp	15 AUG 2020 13:01
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3522082
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 08:00:15

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**	97.3 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

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

PC Time Stamp	16 AUG 2020 19:31
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 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**	96.6 °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	17 AUG 2020 19:05
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

FDA-CBER-2022-1614-0811358

US3522082

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:00:15

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	11 AUG 2020 15:20
PC Open Date & Time	11 AUG 2020 15:17
PC Close Date & Time	11 AUG 2020 17:47

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ⬤
	Does not interfere with activity ◯
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ◯
	Any use of prescription pain reliever or prevents daily activity ◯
Is there any **REDNESS AT INJECTION SITE**?	Yes ◯
	No ⬤
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ◯
	No ⬤
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ⬤
	Does not interfere with activity ◯
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ◯
	Any use of prescription pain reliever or prevents daily activity ◯
PC Time Stamp	11 AUG 2020 18:52
PC Open Date & Time	11 AUG 2020 18:42
PC Close Date & Time	12 AUG 2020 11:59

US3522082
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 08:00:15

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	12 AUG 2020 12:06
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3522082

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:00:15

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	13 AUG 2020 12:16
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3522082

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:00:15

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	14 AUG 2020 17:28
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 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	15 AUG 2020 13:01
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3522082

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:00:15

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	16 AUG 2020 19:32
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3522082

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:00:15

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

US3522082
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 08:00:15

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	◯

US3522082
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 08:00:15

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

PC Time stamp	11 AUG 2020 15:21
PC Open Date & Time	11 AUG 2020 15:17
PC Close Date & Time	11 AUG 2020 17:47

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	11 AUG 2020 18:51
PC Open Date & Time	11 AUG 2020 18:42
PC Close Date & Time	12 AUG 2020 11:59

US3522082

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:00:15

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	12 AUG 2020 12:05
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3522082

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:00:15

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	13 AUG 2020 12:16
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3522082

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:00:15

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 ●

US3522082

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:00:15

	Yes ◯
PC Time stamp	14 AUG 2020 17:29
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3522082
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 08:00:15

TIMEPOINT	DAY 5

HEADACHE

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

FATIGUE

None	⬤
No interference with activity	⭘
Some interference with activity	⭘
Significant; prevents daily activity	⭘

MUSCLE ACHES ALL OVER BODY

None	⬤
No interference with activity	⭘
Some interference with activity	⭘
Significant; prevents daily activity	⭘

JOINT ACHES IN SEVERAL JOINTS

None	⬤
No interference with activity	⭘
Some interference with activity	⭘
Significant; prevents daily activity	⭘

NAUSEA/VOMITING

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

CHILLS

None	⬤
No interference with activity	⭘
Some interference with activity not requiring medical attention	⭘
Prevents daily activity and requires medical attention	⭘

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

	Yes ◯
PC Time stamp	15 AUG 2020 13:02
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

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	16 AUG 2020 19:32
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

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

US3522082
Folder: Safety Call Day 8 (1)
Form: Safety Call
Data signed: (b) (4) **16 Feb 2021 17:06:52**
Generated On: 10 Jun 2021 08:00:15

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

Date of Contact or Contact Attempt *(dd MMM yyyy)* — 18 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3522082

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) **16 Feb 2021 17:06:52**

Generated On: 10 Jun 2021 08:00:15

Is the participant continuing to the next visit?   Yes ●

No ○

Continuing Flag   1

US3522082

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) **16 Feb 2021 17:06:52**

Generated On: 10 Jun 2021 08:00:15

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	MISSED CALL ON 26 AUG 2020 AND CALLED CENTER BACK TODAY. NO ONGOING OR NEW AE REPORTED, NO NEW ILLNESS OR HOSPITAL VISITS; NO CHANGES IN HEALTH STATUS, MEDICATIONS, COVID-19 EXPOSURE
If Contact Not Made, please provide Comments	

US3522082

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) **16 Feb 2021 17:06:51**

Generated On: 10 Jun 2021 08:00:15

Is the participant continuing to the next visit?   Yes ●

No ◯

Continuing Flag   1

US3522082

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) **16 Feb 2021 17:06:52**

Generated On: 10 Jun 2021 08:00:15

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

| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 1 SEP 2020 |

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

| Comments | LEFT A VOICEMAIL |

If Contact Not Made, please provide Comments

US3522082

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) **16 Feb 2021 17:06:52**

Generated On: 10 Jun 2021 08:00:15

Is the participant continuing to the next visit?   Yes ●

                                                                         No ○

Continuing Flag   1

US3522082

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) **16 Feb 2021 17:06:52**

Generated On: 10 Jun 2021 08:00:15

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

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4)   **16 Feb 2021 17:06:52**

Generated On: 10 Jun 2021 08:00:15

Timepoint	Pre-Dose ●
	Post-Dose ○
Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	8 SEP 2020
Time of assessment *(00:00-23:59)*	13:35 (24 HR)
Vital Signs Date and Time (derived)	8 SEP 2020 13:35
Temperature *(xxx.x)*	97.2 F
Route of measurement	Oral ○
	Axillary ○
	Other ●
If Other, specify	TEMPORAL
Pulse *(xxx)*	84 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	84 mmHg
Diastolic Blood Pressure units	MMHG

US3522082

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) **16 Feb 2021 17:06:52**

Generated On: 10 Jun 2021 08:00:15

Timepoint	Pre-Dose ⚪
	Post-Dose ⬤
Were vital signs assessed?	Yes ⬤
	No ⚪
Date of assessment *(dd MMM yyyy)*	8 SEP 2020
Time of assessment *(00:00-23:59)*	15:50 (24 HR)
Vital Signs Date and Time (derived)	8 SEP 2020 15:50
Temperature *(xxx.x)*	97.3 F
Route of measurement	Oral ⚪
	Axillary ⚪
	Other ⬤
If Other, specify	TEMPORAL
Pulse *(xxx)*	71 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	76 mmHg
Diastolic Blood Pressure units	MMHG

US3522082

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) **16 Feb 2021 17:06:52**

Generated On: 10 Jun 2021 08:00:15

Was the physical examination performed?　　　　　　　　Yes ●

　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　No ○

Date of examination *(dd MMM yyyy)*　　　　　　　　　　8 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)*	8 SEP 2020
What was the treatment time? *(00:00-23:59)*	15:20 (24 HR)
Treatment Date and Time (derived)	8 SEP 2020 15:20
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

US3522082

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) **16 Feb 2021 17:06:52**

Generated On: 10 Jun 2021 08:00:15

Was the sample collected?	Yes	●
	No	○

Collection date *(dd MMM yyyy)*	8 SEP 2020
Collection time *(00:00-23:59)*	13:47 (24 HR)
Collection date and time (derived)	8 SEP 2020 13:47

US3522082

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) **16 Feb 2021 17:06:52**

Generated On: 10 Jun 2021 08:00:15

Collection date *(dd MMM yyyy)* 8 SEP 2020

Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:52	8 SEP 2020 13:52
Nasopharyngeal Swab 2	No		

FDA-CBER-2022-1614-0811395

US3522082

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) **16 Feb 2021 17:06:52**

Generated On: 10 Jun 2021 08:00:15

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**	97.3 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	08 SEP 2020 15:50
PC Open Date & Time	08 SEP 2020 15:40
PC Close Date & Time	08 SEP 2020 18:10

TIMEPOINT	DAY 1, AFTER VACCINATION
	(AT HOME)

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

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

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

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

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

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

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

Please record your **TEMPERATURE in °F**	96.8 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

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

PC Time Stamp	08 SEP 2020 22:17
PC Open Date & Time	08 SEP 2020 19:05
PC Close Date & Time	09 SEP 2020 11:59

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.

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	96.4 °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	09 SEP 2020 20:44
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3522082

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:00:15

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	96.7 °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	10 SEP 2020 15:48
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3522082

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:00:15

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**	96.5 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●

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

PC Time Stamp	11 SEP 2020 19:58
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

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.

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

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

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

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

Please record your **TEMPERATURE** in °F	96.7 °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 SEP 2020 13:18
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

TIMEPOINT	DAY 6

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

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

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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	13 SEP 2020 16:39
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3522082

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:00:15

TIMEPOINT	DAY 7

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

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

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

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

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

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

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

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

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

PC Time Stamp	14 SEP 2020 18:47
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3522082

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:00:15

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	08 SEP 2020 15:41
PC Open Date & Time	08 SEP 2020 15:40
PC Close Date & Time	08 SEP 2020 18:10

US3522082

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:00:15

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.	7
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ⬤ Does not interfere with activity ⬭ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ⬭ Any use of prescription pain reliever or prevents daily activity ⬭
PC Time Stamp	08 SEP 2020 22:20
PC Open Date & Time	08 SEP 2020 19:05
PC Close Date & Time	09 SEP 2020 11:59

US3522082

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:00:15

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	09 SEP 2020 20:45
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3522082

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:00:15

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	10 SEP 2020 15:49
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3522082

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:00:15

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	11 SEP 2020 19:57
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 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	12 SEP 2020 13:19
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 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	13 SEP 2020 16:39
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 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	14 SEP 2020 18:47
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

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

HEADACHE

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

FATIGUE

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

MUSCLE ACHES ALL OVER BODY

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

JOINT ACHES IN SEVERAL JOINTS

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

NAUSEA/VOMITING

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

CHILLS

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

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ⬤ Yes ◯
PC Time stamp	08 SEP 2020 15:42
PC Open Date & Time	08 SEP 2020 15:40
PC Close Date & Time	08 SEP 2020 18:10

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	08 SEP 2020 22:21
PC Open Date & Time	08 SEP 2020 19:05
PC Close Date & Time	09 SEP 2020 11:59

US3522082

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:00:15

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 ●

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	Yes ◯
PC Time stamp	09 SEP 2020 20:46
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3522082
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 08:00:15

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 ●

US3522082
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 08:00:15

	Yes ◯
PC Time stamp	10 SEP 2020 15:49
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3522082
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 08:00:15

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	11 SEP 2020 19:57
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

TIMEPOINT	DAY 5

HEADACHE

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

FATIGUE

- None ⬤
- No interference with activity ◯
- Some interference with activity ◯
- Significant; prevents daily activity ◯

MUSCLE ACHES ALL OVER BODY

- None ⬤
- No interference with activity ◯
- Some interference with activity ◯
- Significant; prevents daily activity ◯

JOINT ACHES IN SEVERAL JOINTS

- None ⬤
- No interference with activity ◯
- Some interference with activity ◯
- Significant; prevents daily activity ◯

NAUSEA/VOMITING

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

CHILLS

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

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

US3522082

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:00:15

	Yes ◯
PC Time stamp	12 SEP 2020 13:19
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

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	13 SEP 2020 16:40
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

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	14 SEP 2020 18:48
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3522082

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) **16 Feb 2021 17:06:52**

Generated On: 10 Jun 2021 08:00:15

Was Contact Attempted?	Yes ●
	No ○
Date of Contact or Contact Attempt *(dd MMM yyyy)*	15 SEP 2020
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ○

Comments

If Contact Not Made, please provide Comments

"NO ONGOING OR NEW AE REPORTED, NO NEW ILLNESS OR HOSPITAL VISITS; NO CHANGES IN HEALTH STATUS, MEDICATIONS, COVID-19 EXPOSURE OR PREGNANCY RISK."

US3522082

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) **16 Feb 2021 17:06:52**

Generated On: 10 Jun 2021 08:00:15

Is the participant continuing to the next visit?   Yes ●

                                                                                                                      No ○

Continuing Flag   1

US3522082

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) **16 Feb 2021 17:06:52**

Generated On: 10 Jun 2021 08:00:15

Was Contact Attempted?	Yes ⬤
	No ◯
Date of Contact or Contact Attempt *(dd MMM yyyy)*	22 SEP 2020
Please select one status for the follow-up contact	Contact Made ⬤
	Contact Not Made ◯

Comments

If Contact Not Made, please provide Comments

NO ONGOING OR NEW AE REPORTED, NO NEW ILLNESS OR HOSPITAL VISITS; NO CHANGES IN HEALTH STATUS, MEDICATIONS, COVID-19 EXPOSURE OR PREGNANCY RISK.

US3522082

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) **16 Feb 2021 17:06:52**

Generated On: 10 Jun 2021 08:00:15

Is the participant continuing to the next visit?   Yes ●

No ○

Continuing Flag   1

US3522082

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) **16 Feb 2021 17:06:52**

Generated On: 10 Jun 2021 08:00:15

Was Contact Attempted?	Yes ●
	No ○
Date of Contact or Contact Attempt *(dd MMM yyyy)*	30 SEP 2020
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ○
Comments	NO ONGOING OR NEW AE REPORTED, NO NEW ILLNESS
If Contact Not Made, please provide Comments	OR HOSPITAL VISITS; NO CHANGES IN HEALTH STATUS, MEDICATIONS, COVID-19 EXPOSURE OR PREGNANCY RISK.

US3522082

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) **16 Feb 2021 17:06:52**

Generated On: 10 Jun 2021 08:00:15

Is the participant continuing to the next visit?   Yes ⬤

                                                                                              No ◯

Continuing Flag   1

Was this visit performed?   Yes ●

                                                                                    No ○

Visit date (dd MMM yyyy)   2 OCT 2020

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

                                                                                Clinic ●

Folder OID   VISIT3

US3522082

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) **16 Feb 2021 17:06:52**

Generated On: 10 Jun 2021 08:00:15

Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	2 OCT 2020
Time of assessment *(00:00-23:59)*	08:26 (24 HR)
Vital Signs Date and Time (derived)	2 OCT 2020 08:26
Temperature *(xxx.x)*	97.0 F
Route of measurement	Oral ○
	Axillary ○
	Other ●
If Other, specify	TEMPORAL
Pulse *(xxx)*	77 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	77 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3522082

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) **16 Feb 2021 17:06:52**

Generated On: 10 Jun 2021 08:00:15

Was the physical examination performed?   Yes ●

No ◯

Date of examination *(dd MMM yyyy)*   2 OCT 2020

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

Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **16 Feb 2021 17:06:52**
Generated On: 10 Jun 2021 08:00:15

Was the sample collected?	Yes ●
	No ○
Collection date *(dd MMM yyyy)*	2 OCT 2020
Collection time *(00:00-23:59)*	08:40 (24 HR)
Collection date and time (derived)	2 OCT 2020 08:40

US3522082

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) **16 Feb 2021 17:06:52**

Generated On: 10 Jun 2021 08:00:15

Is the participant continuing to the next visit? Yes ●

No ○

Continuing Flag 1

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 10:19:57
Patient Cloud Open Date & Time	11 OCT 2020 00:01
Patient Cloud Close Date & Time	15 OCT 2020 23:59

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤
	Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤
	Yes ◯
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 OCT 2020 08:25:35
Patient Cloud Open Date & Time	18 OCT 2020 00:01
Patient Cloud Close Date & Time	22 OCT 2020 23:59

US3522082

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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	25 OCT 2020 09:59:21
Patient Cloud Open Date & Time	25 OCT 2020 00:01
Patient Cloud Close Date & Time	29 OCT 2020 23:59

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	08 NOV 2020 00:49:39
Patient Cloud Open Date & Time	08 NOV 2020 00:01
Patient Cloud Close Date & Time	12 NOV 2020 23:59

US3522082

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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	15 NOV 2020 09:29:20
Patient Cloud Open Date & Time	15 NOV 2020 00:01
Patient Cloud Close Date & Time	19 NOV 2020 23:59

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ◯
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 NOV 2020 17:52:29
Patient Cloud Open Date & Time	19 NOV 2020 00:01
Patient Cloud Close Date & Time	23 NOV 2020 23:59

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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 18:26:50
Patient Cloud Open Date & Time	26 NOV 2020 00:01
Patient Cloud Close Date & Time	30 NOV 2020 23:59

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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	03 DEC 2020 18:23:50
Patient Cloud Open Date & Time	03 DEC 2020 00:01
Patient Cloud Close Date & Time	07 DEC 2020 23:59

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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	10 DEC 2020 09:35:07
Patient Cloud Open Date & Time	10 DEC 2020 00:01
Patient Cloud Close Date & Time	14 DEC 2020 23:59

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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	17 DEC 2020 00:04:18
Patient Cloud Open Date & Time	17 DEC 2020 00:01
Patient Cloud Close Date & Time	21 DEC 2020 23:59

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15

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	28 DEC 2020 16:25:54
Patient Cloud Open Date & Time	24 DEC 2020 00:01
Patient Cloud Close Date & Time	28 DEC 2020 23:59

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	31 DEC 2020 15:40:25
Patient Cloud Open Date & Time	31 DEC 2020 00:01
Patient Cloud Close Date & Time	04 JAN 2021 23:59

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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 14:51:11
Patient Cloud Open Date & Time	07 JAN 2021 00:01
Patient Cloud Close Date & Time	11 JAN 2021 23:59

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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	14 JAN 2021 22:08:32
Patient Cloud Open Date & Time	14 JAN 2021 00:01
Patient Cloud Close Date & Time	18 JAN 2021 23:59

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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	21 JAN 2021 14:47:03
Patient Cloud Open Date & Time	21 JAN 2021 00:01
Patient Cloud Close Date & Time	25 JAN 2021 23:59

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15

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	28 JAN 2021 11:32:14
Patient Cloud Open Date & Time	28 JAN 2021 00:01
Patient Cloud Close Date & Time	01 FEB 2021 23:59

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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	04 FEB 2021 12:54:29
Patient Cloud Open Date & Time	04 FEB 2021 00:01
Patient Cloud Close Date & Time	08 FEB 2021 23:59

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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	11 FEB 2021 08:42:18
Patient Cloud Open Date & Time	11 FEB 2021 00:01
Patient Cloud Close Date & Time	15 FEB 2021 23:59

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	18 FEB 2021 02:36:51
Patient Cloud Open Date & Time	18 FEB 2021 00:01
Patient Cloud Close Date & Time	22 FEB 2021 23:59

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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	25 FEB 2021 14:59:49
Patient Cloud Open Date & Time	25 FEB 2021 00:01
Patient Cloud Close Date & Time	01 MAR 2021 23:59

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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	04 MAR 2021 01:15:23
Patient Cloud Open Date & Time	04 MAR 2021 00:01
Patient Cloud Close Date & Time	08 MAR 2021 23:59

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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	11 MAR 2021 12:53:58
Patient Cloud Open Date & Time	11 MAR 2021 00:01
Patient Cloud Close Date & Time	15 MAR 2021 23:59

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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	18 MAR 2021 01:14:08
Patient Cloud Open Date & Time	18 MAR 2021 00:01
Patient Cloud Close Date & Time	22 MAR 2021 23:59

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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	25 MAR 2021 17:21:22
Patient Cloud Open Date & Time	25 MAR 2021 00:01
Patient Cloud Close Date & Time	29 MAR 2021 23:59

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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	05 APR 2021 09:54:52
Patient Cloud Open Date & Time	01 APR 2021 00:01
Patient Cloud Close Date & Time	05 APR 2021 23:59

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15

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	08 APR 2021 00:32:08
Patient Cloud Open Date & Time	08 APR 2021 00:01
Patient Cloud Close Date & Time	12 APR 2021 23:59

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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	15 APR 2021 06:41:36
Patient Cloud Open Date & Time	15 APR 2021 00:01
Patient Cloud Close Date & Time	19 APR 2021 23:59

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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 14:08:06
Patient Cloud Open Date & Time	22 APR 2021 00:01
Patient Cloud Close Date & Time	26 APR 2021 23:59

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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 13:27:44
Patient Cloud Open Date & Time	29 APR 2021 00:01
Patient Cloud Close Date & Time	03 MAY 2021 23:59

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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 ◯

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2021 00:01
Patient Cloud Close Date & Time	10 MAY 2021 23:59

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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-2022-1614-0811473

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2021 00:01
Patient Cloud Close Date & Time	31 MAY 2021 23:59

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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):

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 ◯

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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):

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 ⭕

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

TIMEPOINT	DAY 313

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

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

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

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

FDA-CBER-2022-1614-0811481

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2021 00:01
Patient Cloud Close Date & Time	21 JUN 2021 23:59

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2021 00:01
Patient Cloud Close Date & Time	28 JUN 2021 23:59

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2021 00:01
Patient Cloud Close Date & Time	05 JUL 2021 23:59

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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 ◯

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2021 00:01
Patient Cloud Close Date & Time	12 JUL 2021 23:59

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

TIMEPOINT	**DAY 341**

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

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

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

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

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

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

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

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

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2021 00:01
Patient Cloud Close Date & Time	19 JUL 2021 23:59

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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):

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-2022-1614-0811491

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2021 00:01
Patient Cloud Close Date & Time	26 JUL 2021 23:59

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2021 00:01
Patient Cloud Close Date & Time	02 AUG 2021 23:59

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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 ≥ 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-2022-1614-0811495

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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

Have you been exposed to someone with known SARS-CoV-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 ◯

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2021 00:01
Patient Cloud Close Date & Time	30 AUG 2021 23:59

TIMEPOINT   DAY 390

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

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

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

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

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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):

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 ◯

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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):

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 ◯

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2021 00:01
Patient Cloud Close Date & Time	04 OCT 2021 23:59

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-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-2022-1614-0811513

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

TIMEPOINT   DAY 432

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

FDA-CBER-2022-1614-0811515

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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):

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 ◯

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15

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

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-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-2022-1614-0811519

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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 ◯

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

TIMEPOINT	**DAY 460**

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

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

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

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

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2021 00:01
Patient Cloud Close Date & Time	29 NOV 2021 23:59

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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 ⬭

FDA-CBER-2022-1614-0811531

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Have you been exposed to someone with known SARS-CoV-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-2022-1614-0811533

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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 ◯

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2021 00:01
Patient Cloud Close Date & Time	03 JAN 2022 23:59

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

TIMEPOINT DAY 516

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

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

Fever (Temperature ≥ 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 ◯

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JAN 2022 00:01
Patient Cloud Close Date & Time	10 JAN 2022 23:59

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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 ≥ 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 ◯

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JAN 2022 00:01
Patient Cloud Close Date & Time	17 JAN 2022 23:59

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

TIMEPOINT   DAY 530

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

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

Symptom	
Fever (Temperature ≥ 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-2022-1614-0811543

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JAN 2022 00:01
Patient Cloud Close Date & Time	24 JAN 2022 23:59

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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

Have you been exposed to someone with known SARS-CoV-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 ⬭

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JAN 2022 00:01
Patient Cloud Close Date & Time	31 JAN 2022 23:59

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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 ◯

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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 ◯

FDA-CBER-2022-1614-0811549

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Please contact your study clinic immediately. Click below to confirm that you have read this 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 FEB 2022 00:01
Patient Cloud Close Date & Time	14 FEB 2022 23:59

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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):

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-2022-1614-0811551

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Please contact your study clinic immediately. Click below to confirm that you have read this 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 FEB 2022 00:01
Patient Cloud Close Date & Time	21 FEB 2022 23:59

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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

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

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

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

FDA-CBER-2022-1614-0811553

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Please contact your study clinic immediately. Click below to confirm that you have read this 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 FEB 2022 00:01
Patient Cloud Close Date & Time	28 FEB 2022 23:59

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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 ◯

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

TIMEPOINT <div align="right">DAY 579</div>

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

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAR 2022 00:01
Patient Cloud Close Date & Time	14 MAR 2022 23:59

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAR 2022 00:01
Patient Cloud Close Date & Time	21 MAR 2022 23:59

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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):

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-2022-1614-0811561

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAR 2022 00:01
Patient Cloud Close Date & Time	28 MAR 2022 23:59

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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 ◯

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAR 2022 00:01
Patient Cloud Close Date & Time	04 APR 2022 23:59

TIMEPOINT DAY 607

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

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

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

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

FDA-CBER-2022-1614-0811565

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Please contact your study clinic immediately. Click below to confirm that you have read this 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 APR 2022 00:01
Patient Cloud Close Date & Time	11 APR 2022 23:59

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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 $\geq$ 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 ◯

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Please contact your study clinic immediately. Click below to confirm that you have read this 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 APR 2022 00:01
Patient Cloud Close Date & Time	18 APR 2022 23:59

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):

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 ⬭

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Please contact your study clinic immediately. Click below to confirm that you have read this 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 APR 2022 00:01
Patient Cloud Close Date & Time	25 APR 2022 23:59

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

TIMEPOINT DAY 628

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

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

Fever (Temperature $\geq$ 100.4°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

FDA-CBER-2022-1614-0811571

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Please contact your study clinic immediately. Click below to confirm that you have read this 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 APR 2022 00:01
Patient Cloud Close Date & Time	02 MAY 2022 23:59

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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):

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 ◯

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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 ≥ 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 ◯

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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 ◯

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAY 2022 00:01
Patient Cloud Close Date & Time	30 MAY 2022 23:59

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2022 00:01
Patient Cloud Close Date & Time	06 JUN 2022 23:59

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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 ≥ 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-2022-1614-0811583

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2022 00:01
Patient Cloud Close Date & Time	13 JUN 2022 23:59

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):

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-2022-1614-0811585

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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):

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 ⭘

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2022 00:01
Patient Cloud Close Date & Time	27 JUN 2022 23:59

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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 ◯

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2022 00:01
Patient Cloud Close Date & Time	04 JUL 2022 23:59

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

TIMEPOINT   DAY 698

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

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

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

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

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2022 00:01
Patient Cloud Close Date & Time	11 JUL 2022 23:59

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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):

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-2022-1614-0811593

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2022 00:01
Patient Cloud Close Date & Time	18 JUL 2022 23:59

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):

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 ◯

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2022 00:01
Patient Cloud Close Date & Time	25 JUL 2022 23:59

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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 ◯

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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 ⬭ |

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2022 00:01
Patient Cloud Close Date & Time	08 AUG 2022 23:59

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

TIMEPOINT   **DAY 733**

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

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

Fever (Temperature $\geq$ 100.4°F/38°C) _____

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2022 00:01
Patient Cloud Close Date & Time	15 AUG 2022 23:59

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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 ◯

FDA-CBER-2022-1614-0811603

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2022 00:01
Patient Cloud Close Date & Time	22 AUG 2022 23:59

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-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-2022-1614-0811605

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2022 00:01
Patient Cloud Close Date & Time	29 AUG 2022 23:59

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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):

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 ◯

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2022 00:01
Patient Cloud Close Date & Time	05 SEP 2022 23:59

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2022 00:01
Patient Cloud Close Date & Time	12 SEP 2022 23:59

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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 ≥ 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 ◯

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2022 00:01
Patient Cloud Close Date & Time	19 SEP 2022 23:59

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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 ◯

FDA-CBER-2022-1614-0811613

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2022 00:01
Patient Cloud Close Date & Time	26 SEP 2022 23:59

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

TIMEPOINT   DAY 782

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

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

Fever (Temperature ≥ 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 ◯

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2022 00:01
Patient Cloud Close Date & Time	03 OCT 2022 23:59

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2022 00:01
Patient Cloud Close Date & Time	10 OCT 2022 23:59

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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 ◯

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2022 00:01
Patient Cloud Close Date & Time	17 OCT 2022 23:59

US3522082

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 08:00:15

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		27 FEB 2021 19:45:27

US3522082

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) **21 Feb 2021 21:20:17**

Generated On: 10 Jun 2021 08:00:15

Was Contact Attempted?	Yes ●
	No ○
Date of Contact or Contact Attempt *(dd MMM yyyy)*	4 NOV 2020
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ○

Comments

If Contact Not Made, please provide Comments

"NO ONGOING OR NEW AE REPORTED, NO NEW ILLNESS OR HOSPITAL VISITS; NO CHANGES IN HEALTH STATUS, MEDICATIONS, COVID-19 EXPOSURE OR PREGNANCY RISK."

US3522082

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) **21 Feb 2021 21:20:17**

Generated On: 10 Jun 2021 08:00:15

Is the participant continuing to the next visit?   Yes ●

                                                                                                                        No ◯

Continuing Flag   1

US3522082

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) **21 Feb 2021 21:20:17**

Generated On: 10 Jun 2021 08:00:15

| 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

NO ONGOING OR NEW AE REPORTED, NO NEW ILLNESS OR HOSPITAL VISITS; NO CHANGES IN HEALTH STATUS, MEDICATIONS, COVID-19 EXPOSURE

US3522082

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) **21 Feb 2021 21:20:17**

Generated On: 10 Jun 2021 08:00:15

Is the participant continuing to the next visit? Yes ⬤

No ◯

Continuing Flag 1

US3522082

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) **21 Feb 2021 21:20:17**

Generated On: 10 Jun 2021 08:00:15

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	NO ONGOING OR NEW AE REPORTED, NO NEW ILLNESS OR HOSPITAL VISITS; NO CHANGES IN HEALTH STATUS, MEDICATIONS, COVID-19 EXPOSURE
If Contact Not Made, please provide Comments	

US3522082

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) **21 Feb 2021 21:20:17**

Generated On: 10 Jun 2021 08:00:15

Is the participant continuing to the next visit?   Yes ⬤

No ◯

Continuing Flag   1

US3522082

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) **21 Feb 2021 21:20:17**

Generated On: 10 Jun 2021 08:00:15

Was Contact Attempted?	Yes ●
	No ○
Date of Contact or Contact Attempt *(dd MMM yyyy)*	4 FEB 2021
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ○

Comments

If Contact Not Made, please provide Comments

HAS AN ICD IMPLANT WITH A MONITOR AND CARDIOLOGIST CALLED HIM YESTERDAY TO INFORM HIM THAT HIS HEART BEAT WAS NOT NORMAL (SKIPPING); HE ALSO TOLD HER THAT HE HAD CHEST PAIN LAST NIGHT

US3522082

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) **21 Feb 2021 21:20:17**

Generated On: 10 Jun 2021 08:00:15

Is the participant continuing to the next visit?   Yes ●

No ◯

Continuing Flag   1

US3522082

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) **09 Mar 2021 15:35:28**

Generated On: 10 Jun 2021 08:00:15

Was this visit performed?	Yes ⬤
	No ◯
Visit date (dd MMM yyyy)	8 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home ◯
	Clinic ⬤
Folder OID	VISIT4

Were vital signs assessed?	Yes ◯
	No ⬤

Date of assessment *(dd MMM yyyy)*	_____
Time of assessment *(00:00-23:59)*	_____
Vital Signs Date and Time (derived)	_____
Temperature *(xxx.x)*	_____
Route of measurement	Oral ◯
	Axillary ◯
	Other ◯
If Other, specify	_____
Pulse *(xxx)*	_____
Pulse units	_____
Respiratory Rate *(xxx)*	_____
Respiratory Rate units	_____
Systolic Blood Pressure *(xxx)*	_____
Systolic Blood Pressure units	_____
Diastolic Blood Pressure *(xxx)*	_____
Diastolic Blood Pressure units	_____
Height (derived)	_____
Weight (derived)	_____

FDA-CBER-2022-1614-0811631

US3522082

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) **09 Mar 2021 15:35:28**

Generated On: 10 Jun 2021 08:00:15

Was the physical examination performed?　　　　　　　　　　Yes ●

　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　No ○

Date of examination *(dd MMM yyyy)*　　　　　　　　　　　　8 MAR 2021

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

US3522082

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) **09 Mar 2021 15:35:28**

Generated On: 10 Jun 2021 08:00:15

Was the sample collected?	Yes ⬤
	No ◯
Collection date *(dd MMM yyyy)*	8 MAR 2021
Collection time *(00:00-23:59)*	10:02 (24 HR)
Collection date and time (derived)	8 MAR 2021 10:02

US3522082

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) **09 Mar 2021 15:35:28**

Generated On: 10 Jun 2021 08:00:15

Is the participant continuing to the next visit?   Yes ●

                                                                                            No ○

Continuing Flag   1

US3522082

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) **12 Apr 2021 11:52:25**

Generated On: 10 Jun 2021 08:00:15

Was Contact Attempted?	Yes ●
	No ○
Date of Contact or Contact Attempt *(dd MMM yyyy)*	6 APR 2021
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ○
Comments *If Contact Not Made, please provide Comments*	REPORTS THAT HIS HEALTH IS CURRENTLY STABLE, THOUGH STILL HAS PERSISTENT CHEST CONGESTION, AND IS DUE FOR A PCP FOLLOW UP ON FRIDAY, 09 APR 2021; NO OTHER CHANGES REPORTED, NO COVID-19 EXPOSURE

US3522082

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) **12 Apr 2021 11:52:25**

Generated On: 10 Jun 2021 08:00:15

Is the participant continuing to the next visit?   Yes ●

                                                                                    No ◯

Continuing Flag   1

US3522082
Folder: Safety Call Day 269 (1)
Form: Safety Call
Generated On: 10 Jun 2021 08:00:15

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 _____

US3522082

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:00:15

Is the participant continuing to the next visit?　　　　　　　　　　　　Yes ◯

　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　No ◯

Continuing Flag

US3522082
Folder: Covid-19 Assessment (1)
Form: COVID-19 Contact
Generated On: 10 Jun 2021 08:00:15

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 ◯

US3522082

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 08:00:15

Generate Next COVID-19 Assessment	Yes ◯
	No ◯

US3522082

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

Form: Visit Date

Data signed: (b) (4) **21 Feb 2021 21:20:17**

Generated On: 10 Jun 2021 08:00:15

| Was this visit performed? | Yes ● |
| | No ○ |

Visit date (dd MMM yyyy)	28 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●

| Folder OID | UNBLND_DECIDE |

US3522082

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

Form: Unblinding

Data signed: (b) (4) **19 Mar 2021 18:01:28**

Generated On: 10 Jun 2021 08:00:15

Date of updated informed consent *(dd MMM yyyy)*	28 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)*	28 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) **21 Feb 2021 21:20:17**

Generated On: 10 Jun 2021 08:00:15

Was the sample collected?	Yes ●
	No ○
Collection date *(dd MMM yyyy)*	28 JAN 2021
Collection time *(00:00-23:59)*	10:25 (24 HR)
Collection date and time (derived)	28 JAN 2021 10:25

US3522082

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) **21 Feb 2021 21:20:17**

Generated On: 10 Jun 2021 08:00:15

Was the sample collected?	Yes ●
	No ○
Collection date *(dd MMM yyyy)*	28 JAN 2021
Collection time *(00:00 - 23:59)*	10:30
Collection Date and Time (derived)	28 JAN 2021 10:30

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) **21 Feb 2021 21:20:17**

Generated On: 10 Jun 2021 08:00:15

Did the participant experience any adverse events?   Yes ●

No ◯

If Yes, enter details on the Adverse Events form.

AEID	
Adverse event	IRREGULAR HEART BEAT
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)*	3 FEB 2021
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, end date *(dd MMM yyyy)*	4 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	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ◯
	No ◯
	Unknown ◯
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Congenital anomaly or birth defect	False
Other medically important event	False

Relationship to investigational product

- Not Related ●
- Related ○
- Not Applicable ○

Relationship to Study Procedure

- Not Related ●
- Related ○
- Not Applicable ○

Action taken with investigational product

- None ○
- Dose Delayed ○
- Investigational Product Withdrawn ○
- Not Applicable ●

Other action taken (check all that apply)

None	True
Concomitant Medication	False
Concomitant Procedure	False

Outcome

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

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

Narrative

HAS AN ICD IMPLANT WITH A MONITOR AND CARDIOLOGIST CALLED HIM YESTERDAY TO INFORM HIM THAT HIS HEART BEAT WAS NOT NORMAL (SKIPPING); HE ALSO TOLD HER THAT HE HAD CHEST PAIN LAST NIGHT SO SHE URGED HIM TO CONTACT HIS PCP WHO ADVISED HIM TO GO TO VA ER TODAY. HE IS ON HIS WAY RIGHT NOW (12:12 ON 04 FEB 2021)

UPDATE ON 10 FEB 2021: STATES THAT AT VA ER VISIT ON 04 FEB 2021, BLOODWORK WAS OK, BUT THEY SCHEDULED HIM FOR A NUCLEAR STRESS TEST WHICH, HE'S DOING TODAY, 10 FEB 2021 (HAS BEEN THERE SINCE MORNING AND HAS 15 MINUTES LEFT). ALSO, HIS CARDIOLOGIST ORDERED A MONITOR PATCH FOR ICD FOR WHICH HE WILL USE FOR TWO DAYS (HE IS STILL WAITING FOR IT TO COME THROUGH THE MAIL). CHEST PAIN RESOLVED ON 04 FEB 2021 AND HE FEELS OK.

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

AEID	
Adverse event	CARDIAC CHEST 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)*	3 FEB 2021
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, end date *(dd MMM yyyy)*	4 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	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ◯
	No ◯
	Unknown ◯
Number of Days in ICU	
Persistent or significant disability or incapacity	False

Congenital anomaly or birth defect	False
Other medically important event	False

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

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

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

Other action taken (check all that apply)

None	True
Concomitant Medication	False
Concomitant Procedure	False

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

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

Narrative

HAS AN ICD IMPLANT WITH A MONITOR AND CARDIOLOGIST CALLED HIM YESTERDAY TO INFORM HIM THAT HIS HEART BEAT WAS NOT NORMAL (SKIPPING); HE ALSO TOLD HER THAT HE HAD CHEST PAIN LAST NIGHT SO SHE URGED HIM TO CONTACT HIS PCP WHO ADVISED HIM TO GO TO VA ER TODAY. HE IS ON HIS WAY RIGHT NOW (12:12 ON 04 FEB 2021)
UPDATE ON 10 FEB 2021: STATES THAT AT VA ER VISIT ON 04 FEB 2021, BLOODWORK WAS OK, BUT THEY SCHEDULED HIM FOR A NUCLEAR STRESS TEST WHICH, HE'S DOING TODAY, 10 FEB 2021 (HAS BEEN THERE SINCE MORNING AND HAS 15 MINUTES LEFT). ALSO, HIS CARDIOLOGIST ORDERED A MONITOR PATCH FOR ICD FOR WHICH HE WILL USE FOR TWO DAYS (HE IS STILL WAITING FOR IT TO COME THROUGH THE MAIL). CHEST PAIN RESOLVED ON 04 FEB 2021 AND HE FEELS OK.

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

AEID	USA-US131-2021-MRNA-1273-P30 1000010
Adverse event	CHEST CONGESTION

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

Was this a Solicited Adverse Reaction?　　Yes ○　No ●

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

Start date *(dd MMM yyyy)*	1 MAR 2021
Start time *(00:00-23:59)*	
AE start date and time (derived)	

Ongoing?　　Yes ●　No ○

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

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

Is the adverse event serious?　　Yes ●　No ○

AE is serious due To (check all that apply)

Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date *(dd MMM yyyy)*	1 MAR 2021
Hospital Discharge Date *(dd MMM yyyy)*	2 MAR 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	False
Concomitant Medication	True
Concomitant Procedure	True

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

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

Narrative

HE SAID HE HAS BEEN DOING WELL BUT WENT FOR A FOLLOW UP ON 01 MAR 2021 AND THEY DID AN X-RAY OF HIS CHEST AND SAW CHEST CONGESTION SO THEY HAD HIM STAY OVERNIGHT FOR OBSERVATION AND HE WAS SWITCHED FROM LISINOPRIL 40 MG ONCE DAILY TO EMPAGLIFLOZIN (JARIDANCE) 10 MG ONCE DAILY FOR THE CHEST CONGESTION. HE WAS ALSO PRESCRIBED SACUBITRIL-VALSARTAN24/26 MG TWICE DAILY, WHICH HE WILL START 05 MAR 2021. HE IS SCHEDULED FOR AN ECHO ON 24 MAR 2021

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

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) **21 Feb 2021 21:20:17**

Generated On: 10 Jun 2021 08:00:15

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

                                                                       No ○

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

Name of Medication	CARVEDILOL

Prophylaxis	Yes ⚪
	No ⚫

Indication	CAD
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)*	
Start date completely unknown	True
Ongoing?	Yes ⬤
	No ◯

If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ⬤

Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ⬤

Name of Medication	ASPIRIN

Prophylaxis	Yes ⚪
	No ⚫

Indication	CAD
Dose per administration	81

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

If dose unit is Other, specify	

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

If frequency is Other, specify	

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

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EAB) (1725)

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

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	
Start date completely unknown	True
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-2022-1614-0811659

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) **12 Apr 2021 11:52:25**

Generated On: 10 Jun 2021 08:00:15

Name of Medication	LASIX

Prophylaxis
- Yes ◯
- No ⬤

Indication	CAD
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)*	
Start date completely unknown	True
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 (4)

Data signed: (b) (4) **12 Apr 2021 11:52:25**

Generated On: 10 Jun 2021 08:00:15

Name of Medication	XARELTO
Prophylaxis	Yes ○
	No ●
Indication	CAD
Dose per administration	UNK
Dose unit	mg ○
	ug ○
	mL ○
	g ○
	IU ○
	tablet ○
	capsule ○
	puff ○
	Other ●
If dose unit is Other, specify	UNKN
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)*

Start date completely unknown   True

Ongoing?   Yes ◯
                                                                                                   No ⬤

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

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

Separate Dosage Number (derived)

Interval Dosage Unit Number (derived)

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

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) **12 Apr 2021 11:52:25**

Generated On: 10 Jun 2021 08:00:15

Name of Medication	APIXABAN

Prophylaxis
- Yes ◯
- No ⬤

Indication	CAD
Dose per administration	2.5

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

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

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

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

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

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) **12 Apr 2021 11:52:25**

Generated On: 10 Jun 2021 08:00:15

Name of Medication	LISINOPRIL

Prophylaxis	Yes ○
	No ●

Indication	HYPERTENSION

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 ○

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EAB) (1725)

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Data signed: (b) (4) **12 Apr 2021 11:52:25**
Generated On: 10 Jun 2021 08:00:15

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)*	
Start date completely unknown	True
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	1 MAR 2021
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	EMPAGLIFLOZIN

Prophylaxis	Yes ◯
	No ⬤

Indication	CAD
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 ◯

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Data signed: (b) (4) **12 Apr 2021 11:52:25**
Generated On: 10 Jun 2021 08:00:15

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)*	1 MAR 2021
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 (8)

Data signed: (b) (4)   **12 Apr 2021 11:52:25**

Generated On: 10 Jun 2021 08:00:15

Name of Medication	FERROUS SULFATE

Prophylaxis

Yes ◯
No ⬤

Indication	IRON DEFICIENCY ANEMIA
Dose per administration	325

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)*	
Start date completely unknown	True
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 (9)

Data signed: (b) (4) **12 Apr 2021 11:52:25**

Generated On: 10 Jun 2021 08:00:15

Name of Medication	ATORVASTATIN

Prophylaxis

Yes ⭘
No ⬤

Indication	CAD
Dose per administration	80

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 ⭘

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Data signed: (b) (4) **12 Apr 2021 11:52:25**
Generated On: 10 Jun 2021 08:00:15

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)*	
Start date completely unknown	True
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	PANTOPRAZOLE

Prophylaxis

Yes ⚪
No ⚫

Indication	GERD
Dose per administration	20

Dose unit

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

If dose unit is Other, specify

Frequency

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

If frequency is Other, specify

Route of administration

Oral ⚫
Topical ⚪
Subcutaneous ⚪
Transdermal ⚪
Intraocular ⚪

FDA-CBER-2022-1614-0811674

	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)*	
Start date completely unknown	True
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	DAILY MULTIVITAMIN

Prophylaxis	Yes ●
	No ○

Indication	DIETARY SUPPLEMENT
Dose per administration	UNKNOWN

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

If dose unit is Other, specify	UNKNOWN

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 ○

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Data signed: (b) (4) **12 Apr 2021 11:52:25**
Generated On: 10 Jun 2021 08:00:15

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)*	
Start date completely unknown	True
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 (12)

Data signed: (b) (4) **12 Apr 2021 11:52:25**

Generated On: 10 Jun 2021 08:00:15

Name of Medication	SACUBITRIL-VALSARTAN

Prophylaxis

Yes ◯
No ⬤

Indication	CAD
Dose per administration	24/26

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)*   5 MAR 2021

Start date completely unknown   False

Ongoing?   Yes ⬤
                                               No ◯

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

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

Separate Dosage Number (derived)   2

Interval Dosage Unit Number (derived)   1

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

US3522082

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) **05 Mar 2021 15:32:00**

Generated On: 10 Jun 2021 08:00:15

Were any concomitant procedures performed?   Yes ●

No ○

If yes, please complete Concomitant Procedures form.

US3522082

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) **19 Mar 2021 18:01:28**

Generated On: 10 Jun 2021 08:00:15

Procedure/Surgery date *(dd MMM yyyy)*	Procedure/Surgery	Indication	If indication is Other, specify
1 MAR 2021	CHEST X-RAY	Adverse Event	
10 FEB 2021	NUCLEAR STRESS TEST	Adverse Event	
10 MAR 2021	BLOODWORK- LACTATE AND ASPARTATE AMINOTRANSFERASE	Medical History	
11 MAR 2021	BLOODWORK- PTT, PROTIME, PT, NT PRO BNP, MAGNESIUM, CBC W/ DIFF, BMP, WHOLE BLOOD GLUCOSE	Medical History	

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-US131-2021-MRNA-1273-P30 1000010
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	PAUL
Investigator's Last Name	KILGORE
Site Address: Street	(b) (6)
Site Address: City	(b) (6)
Site Address: State	MI
Site Address: Postal Code	(b) (6)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3522082

Folder: SAE USA-US131-2021-MRNA-1273-P301000010

Form: Safety Report Form (1)

Data signed: (b) (4) **19 Mar 2021 18:01:28**

Generated On: 10 Jun 2021 08:00:15

SAEID	USA-US131-2021-MRNA-1273-P30 1000010
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	PAUL
Investigator's Last Name	KILGORE
Site Address: Street	(b) (6)
Site Address: City	(b) (6)
Site Address: State	MI
Site Address: Postal Code	(b) (6)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	05/MAR/2021 15:41
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

US3522082

Folder: SAE USA-US131-2021-MRNA-1273-P301000010

Form: Safety Report Form (2)

Data signed: (b) (4) **19 Mar 2021 18:01:28**

Generated On: 10 Jun 2021 08:00:15

SAEID	USA-US131-2021-MRNA-1273-P30 1000010
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	PAUL
Investigator's Last Name	KILGORE
Site Address: Street	(b) (6)
Site Address: City	(b) (6)
Site Address: State	MI
Site Address: Postal Code	(b) (6)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	17/MAR/2021 13:39
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

US3522082 (Prod: Henry Ford Health System)

US3522082

Form: Participant Creation

Generated On: 10 Jun 2021 08:00:15

Participant ID

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:29:06
User entered 'US3522082'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	11 Aug 2020 17:09:35

US3522082

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:00:15

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:29:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 17:11:10

US3522082

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:00:15

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:29:13
User entered '11 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	11 Aug 2020 17:09:36

US3522082

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:00:15

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 08:39:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:29:13
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	11 Aug 2020 17:11:10

US3522082
Folder: Screening
Form: Visit Date
Generated On: 10 Jun 2021 08:00:15
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
User entered 'SCRN'	System	11 Aug 2020 17:11:10

US3522082
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 08:00:15
Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:30:59
User entered (b) (6) 1957'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	11 Aug 2020 17:09:37

US3522082

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:00:15

Age

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:30:59
User entered '62'	(b) (4), (b) (6)	11 Aug 2020 17:30:19

US3522082
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 08:00:15
Age Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
User entered 'YEARS'	System	11 Aug 2020 17:30:19

US3522082
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 08:00:15
Age (Derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
User entered '62'	System	11 Aug 2020 17:30:33

US3522082

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:00:15

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:30:59
User entered 'Male (M)'	(b) (4), (b) (6)	11 Aug 2020 17:30:19

US3522082
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 08:00:15
Ethnicity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:30:59
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	11 Aug 2020 17:30:19

US3522082

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:00:15

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:30:59
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 17:30:19

US3522082

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:00:15

Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:30:59
User entered '1'	(b) (4), (b) (6)	11 Aug 2020 17:30:19

US3522082
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 08:00:15
Asian

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:30:59
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 17:30:19

US3522082

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:00:15

American Indian or Alaska Native

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:30:59
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 17:30:19

US3522082

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:00:15

Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:30:59
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 17:30:19

US3522082
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 08:00:15
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:30:59
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 17:30:19

US3522082
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 08:00:15
If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:30:59
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 17:30:19

US3522082

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:00:15

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:30:59
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 17:30:19

US3522082

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:00:15

Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:30:59
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 17:30:19

US3522082

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:00:15

Date of Informed Consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:31:03
User entered '11 Aug 2020'	(b) (4), (b) (6)	11 Aug 2020 17:30:33

US3522082

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:00:15

Month and Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
User entered 'Aug 2020'	System	11 Aug 2020 17:30:33

US3522082

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:00:15

Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
User entered '2020'	System	11 Aug 2020 17:30:33

US3522082

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:00:15

Protocol Version

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:31:03
User entered 'Amendment 1 (1)'	(b) (4), (b) (6)	11 Aug 2020 17:30:33

US3522082

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:00:15

Was participant enrolled in the study?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:31:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 17:30:33

US3522082

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:00:15

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:31:03
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 17:30:33

US3522082

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:00:15

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:31:03
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 17:30:33

US3522082

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:00:15

Was this participant screened previously?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:31:03
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Aug 2020 18:35:36
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Aug 2020 18:35:36
User entered 'No (N)' reason for change: Data Entry Error	Sharon Mathys (b) (4)	17 Aug 2020 18:35:36
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Aug 2020 17:30:33
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 17:30:33

US3522082
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 08:00:15
If Yes, previous participant number

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:31:03
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	11 Aug 2020 17:09:36

US3522082

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:00:15

Enrollment Trigger

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
User entered '1'	System	11 Aug 2020 17:30:39

US3522082

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 08:00:15

Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:31:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 17:30:39

US3522082

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 08:00:15

Were any significant conditions reported?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:31:15
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	13 Aug 2020 18:06:16

US3522082

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:00:15

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:45:47
User closed query 'For research purposes please spell out CAD. Thank you.' (Site from CRA).	(b) (4), (b) (6)	25 Feb 2021 05:06:12
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery disease, LLT: Coronary artery disease - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 15:51:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 15:51:48
Data point term sent to Coder	System	14 Sep 2020 15:50:45
Query 'For research purposes please spell out CAD. Thank you.' answered with 'updated' (Site from CRA).	Jelena Verkler (b) (4) (b) (4)	14 Sep 2020 15:50:40
Coding entries removed.	Jelena Verkler (b) (4) (b) (4)	14 Sep 2020 15:50:21
User entered 'Coronary Artery Disease' reason for change: Data Entry Error	Jelena Verkler (b) (4) (b) (4)	14 Sep 2020 15:50:21
User opened query 'For research purposes please spell out CAD. Thank you.' (Site from CRA).	(b) (4), (b) (6)	09 Sep 2020 13:32:28
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery disease, LLT: Coronary artery disease - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 18:07:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 18:07:34
Data point term sent to Coder	System	13 Aug 2020 18:06:42
User entered 'CAD'	Sharon Mathys (b) (4) (b) (4)	13 Aug 2020 18:06:26

US3522082

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:00:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:32:30
User entered empty.	Sharon Mathys (b) (4) (b) (4)	13 Aug 2020 18:06:26

US3522082

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:00:15

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:32:32
User entered '1'	Sharon Mathys (b) (4) (b) (4)	13 Aug 2020 18:06:26

US3522082

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:00:15

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:32:34
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	13 Aug 2020 18:06:26

US3522082

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:00:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:32:35
User entered empty.	Sharon Mathys (b) (4) (b) (4)	13 Aug 2020 18:06:26

US3522082

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:00:15

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:32:36
User entered '0'	Sharon Mathys (b) (4) (b) (4)	13 Aug 2020 18:06:26

US3522082

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:00:15

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
User entered empty.	System	13 Aug 2020 18:06:26

US3522082

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:00:15

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
User entered empty.	System	13 Aug 2020 18:06:26

US3522082

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:00:15

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
User entered empty.	System	13 Aug 2020 18:06:26

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
User entered empty.	System	13 Aug 2020 18:06:26

US3522082

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:00:15

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:51:40
User coded data point as SOC: Surgical and medical procedures, HLGT: Cardiac therapeutic procedures, HLT: Cardiac device therapeutic procedures, PT: Implantable defibrillator insertion, LLT: Implantable cardioverter defibrillator insertion - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Mar 2021 09:02:29
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Mar 2021 09:02:29
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
Data point term sent to Coder	System	23 Feb 2021 14:48:43
User entered 'ICD implant'	(b) (4), (b) (6)	23 Feb 2021 14:48:30

US3522082

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:00:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:51:41
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered empty.	(b) (4), (b) (6)	23 Feb 2021 14:48:30

US3522082

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:00:15

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:51:42
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:32:01
User entered '1'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 14:48:30

US3522082

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:00:15

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:51:44
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:32:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 14:48:30

US3522082

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:00:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:51:45
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:32:01
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 14:48:30

US3522082

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:00:15

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:51:46
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered '0'	(b) (4), (b) (6)	23 Feb 2021 14:48:30

US3522082

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:00:15

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
User entered empty.	System	23 Feb 2021 14:48:30

US3522082
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 08:00:15
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
User entered empty.	System	23 Feb 2021 14:48:30

US3522082

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:00:15

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
User entered empty.	System	23 Feb 2021 14:48:30

US3522082

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:00:15

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
User entered empty.	System	23 Feb 2021 14:48:30

US3522082

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:00:15

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	12 Apr 2021 11:52:25
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 22:26:26
User closed query 'Please provide source for hypertension. Thank you. ' (Site from CRA).	(b) (4), (b) (6)	05 Apr 2021 22:26:00
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Essential hypertension, LLT: Primary hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Apr 2021 13:50:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Apr 2021 13:50:39
Data point term sent to Coder	System	02 Apr 2021 13:49:28
Coding entries removed.	Alayna Wilder (b) (4) (b) (4)	02 Apr 2021 13:48:49
Signature has been broken.	Alayna Wilder (b) (4) (b) (4)	02 Apr 2021 13:48:49
User entered 'Primary HYPERTENSION' reason for change: Data Entry Error	Alayna Wilder (b) (4) (b) (4)	02 Apr 2021 13:48:49
Query 'Please provide source for hypertension. Thank you. ' answered with 'Hypertension is classified as primary or secondary, Pulmonary Hypertension would have been specified it it was PHT, Primary Hypertension is the medical terminology and is appropriate. ' (Site from CRA).	Alayna Wilder (b) (4) (b) (4)	02 Apr 2021 13:48:31
User opened query 'Please provide source for hypertension. Thank you. ' (Site from CRA).	(b) (4), (b) (6)	01 Apr 2021 21:52:05
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
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)	04 Mar 2021 17:11:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Mar 2021 17:11:05
Data point term sent to Coder	System	04 Mar 2021 17:10:11
User entered 'Hypertension'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:09:40

US3522082

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:00:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 22:26:26
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:09:40

US3522082

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:00:15

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 22:26:26
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered '1'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:09:40

US3522082

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:00:15

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 22:26:26
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered 'Yes (Y)'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:09:40

US3522082

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:00:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 22:26:26
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:09:40

US3522082

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:00:15

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 22:26:26
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered '0'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:09:40

US3522082
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 08:00:15
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
User entered empty.	System	04 Mar 2021 17:09:40

US3522082
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 08:00:15
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
User entered empty.	System	04 Mar 2021 17:09:40

US3522082

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:00:15

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
User entered empty.	System	04 Mar 2021 17:09:40

US3522082
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 08:00:15

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
User entered empty.	System	04 Mar 2021 17:09:40

US3522082

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:00:15

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 22:26:26
User closed query 'Please provide source for Iron Deficiency. Thank you' (Site from CRA).	(b) (4), (b) (6)	05 Apr 2021 22:26:12
Query 'Please provide source for Iron Deficiency. Thank you' answered with 'unknown source' (Site from CRA).	Alayna Wilder (b) (4) (b) (4)	02 Apr 2021 13:57:50
User opened query 'Please provide source for Iron Deficiency. Thank you' (Site from CRA).	(b) (4), (b) (6)	01 Apr 2021 21:52:22
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Anaemias nonhaemolytic and marrow depression, HLT: Anaemia deficiencies, PT: Iron deficiency anaemia, LLT: Iron deficiency anemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Mar 2021 17:12:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Mar 2021 17:12:01
Data point term sent to Coder	System	04 Mar 2021 17:11:12
User entered 'iron deficiency anemia'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:10:23

US3522082

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:00:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 22:26:26
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:10:23

US3522082

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:00:15

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 22:26:26
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered '1'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:10:23

US3522082
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 08:00:15
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 22:26:26
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered 'Yes (Y)'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:10:23

US3522082

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:00:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 22:26:26
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:10:23

US3522082

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:00:15

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 22:26:26
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered '0'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:10:23

US3522082
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 08:00:15
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
User entered empty.	System	04 Mar 2021 17:10:23

US3522082
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 08:00:15

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
User entered empty.	System	04 Mar 2021 17:10:23

US3522082
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 08:00:15
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
User entered empty.	System	04 Mar 2021 17:10:23

US3522082
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 08:00:15

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
User entered empty.	System	04 Mar 2021 17:10:23

US3522082

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:00:15

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 22:26:26
User closed query 'Please provide source for GERD. Thank you' (Site from CRA).	(b) (4), (b) (6)	05 Apr 2021 22:26:24
Query 'Please provide source for GERD. Thank you' answered with 'unknown source, this is not common knowledge for most patients and physicians normally treat the symptoms as there are numerous possible causes' (Site from CRA).	Alayna Wilder (b) (4) (b) (4)	02 Apr 2021 13:59:56
User opened query 'Please provide source for GERD. Thank you' (Site from CRA).	(b) (4), (b) (6)	01 Apr 2021 21:52:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastrooesophageal reflux disease, LLT: GERD - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Mar 2021 17:12:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Mar 2021 17:12:01
Data point term sent to Coder	System	04 Mar 2021 17:11:12
User entered 'GERD'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:10:51

US3522082
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 08:00:15
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 22:26:26
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:10:51

US3522082

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:00:15

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 22:26:26
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered '1'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:10:51

US3522082
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 08:00:15
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 22:26:26
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered 'Yes (Y)'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:10:51

US3522082

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:00:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 22:26:26
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:10:51

US3522082

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:00:15

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 22:26:26
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered '0'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:10:51

US3522082
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 08:00:15
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
User entered empty.	System	04 Mar 2021 17:10:51

US3522082

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:00:15

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
User entered empty.	System	04 Mar 2021 17:10:51

US3522082

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:00:15

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
User entered empty.	System	04 Mar 2021 17:10:51

US3522082
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 08:00:15

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
User entered empty.	System	04 Mar 2021 17:10:51

US3522082
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 08:00:15

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:20:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:32:47
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	13 Aug 2020 18:12:54

Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 08:00:15

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:28
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:33:34
User closed query 'Data is required. Please provide.' (Site from System).	System	13 Aug 2020 18:13:11
User entered '11 Aug 2020' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	13 Aug 2020 18:13:11
User opened query 'Data is required. Please provide.' (Site from System).	System	13 Aug 2020 18:12:54
User entered empty.	Sharon Mathys (b) (4) (b) (4)	13 Aug 2020 18:12:54

US3522082

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:00:15

Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:28
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:33:34
User entered '13:30'	Sharon Mathys (b) (4) (b) (4)	13 Aug 2020 18:12:54

US3522082

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:00:15

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
User entered '11 Aug 2020 13:30'	System	13 Aug 2020 18:13:11
User entered empty.	System	13 Aug 2020 18:12:54

US3522082
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 08:00:15

Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:20:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:33:34
User entered '66.5' in	Sharon Mathys (b) (4)	13 Aug 2020 18:12:54
DataPoint set to visible.	(b) (4) System	11 Aug 2020 17:30:39

US3522082

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:00:15

Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:20:28
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:33:34
User entered '155.7' lb	Sharon Mathys (b) (4)	13 Aug 2020 18:12:54
DataPoint set to visible.	System	11 Aug 2020 17:30:39

US3522082
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 08:00:15

BMI *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
Amendment Manager: User entered '24.80591'	System	16 Sep 2020 23:51:54
User entered '24.8'	System	13 Aug 2020 18:12:54
DataPoint set to visible.	System	11 Aug 2020 17:30:39

US3522082
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 08:00:15
BMI units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
User entered 'kg/m2'	System	13 Aug 2020 18:12:54
DataPoint set to visible.	System	11 Aug 2020 17:30:39

US3522082
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 08:00:15
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:28
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:33:34
User entered missing code ND - Not Done.	Sharon Mathys (b) (4) (b) (4)	13 Aug 2020 18:12:54

US3522082
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 08:00:15
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:28
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:33:34
User closed query 'Per CDM : 'ND' noted for Temperature; however please also keep the 'Route of measurement' blank. Thank you.' (Site from DM).	(b) (4), (b) (6)	25 Aug 2020 14:45:41
Query 'Per CDM : 'ND' noted for Temperature; however please also keep the 'Route of measurement' blank. Thank you.' answered with 'done' (Site from DM).	Tyler Prentiss (b) (4) (b) (4)	24 Aug 2020 20:51:02
User entered empty; reason for change Data Entry Error	Tyler Prentiss (b) (4) (b) (4)	24 Aug 2020 20:50:58
User opened query 'Per CDM : 'ND' noted for Temperature; however please also keep the 'Route of measurement' blank. Thank you.' (Site from DM).	(b) (4), (b) (6)	24 Aug 2020 05:01:21
User closed query 'Data is required. Please provide.' (Site from System).	System	13 Aug 2020 18:13:11
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	13 Aug 2020 18:13:11
User entered 'Oral (Oral)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	13 Aug 2020 18:13:11
User opened query 'Data is required. Please provide.' (Site from System).	System	13 Aug 2020 18:12:54
User entered empty.	Sharon Mathys (b) (4) (b) (4)	13 Aug 2020 18:12:54

US3522082
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 08:00:15
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:28
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:33:34
User entered empty.	Sharon Mathys (b) (4) (b) (4)	13 Aug 2020 18:12:54

US3522082
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 08:00:15
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:28
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:33:34
User entered missing code ND - Not Done.	Sharon Mathys (b) (4) (b) (4)	13 Aug 2020 18:12:54

US3522082
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 08:00:15
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
User entered 'bpm'	System	13 Aug 2020 18:12:54

US3522082
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 08:00:15
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:20:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:33:34
User entered missing code ND - Not Done.	Sharon Mathys (b) (4) (b) (4)	13 Aug 2020 18:12:54

US3522082

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:00:15

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
User entered 'breaths/min'	System	13 Aug 2020 18:12:54

US3522082
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 08:00:15
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:28
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:33:34
User entered missing code ND - Not Done.	Sharon Mathys (b) (4) (b) (4)	13 Aug 2020 18:12:54

Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 08:00:15

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
User entered 'mmHg'	System	13 Aug 2020 18:12:54

US3522082
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 08:00:15
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:28
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:33:34
User entered missing code ND - Not Done.	Sharon Mathys (b) (4) (b) (4)	13 Aug 2020 18:12:54

US3522082
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 08:00:15
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
User entered 'mmHg'	System	13 Aug 2020 18:12:54

US3522082

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:00:15

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17

US3522082
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 08:00:15

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17

US3522082

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:00:15

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:33:39
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	13 Aug 2020 18:10:23

US3522082

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:00:15

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
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 12:25:37
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:33:39
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	08 Sep 2020 17:59:36
User entered '11 Aug 2020'	Sharon Mathys (b) (4) (b) (4)	13 Aug 2020 18:10:23

US3522082

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:00:15

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 08:39:17
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:33:59
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	25 Aug 2020 19:08:55

US3522082

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:00:15

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 08:39:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:33:59
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	25 Aug 2020 19:08:55

US3522082

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:00:15

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 08:39:17
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:33:59
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	25 Aug 2020 19:08:55

US3522082

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:00:15

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 08:39:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:33:59
User entered 'No (N)'	Sharon Mathys (b) (4)	25 Aug 2020 19:08:55

US3522082

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:00:15

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 08:39:17
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:33:59
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	25 Aug 2020 19:08:55

US3522082

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:00:15

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 08:39:17
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:33:59
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	25 Aug 2020 19:08:55

US3522082

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:00:15

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 08:39:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:33:59
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	25 Aug 2020 19:08:55

US3522082

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:00:15

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 08:39:17
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:33:59
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	25 Aug 2020 19:08:55

US3522082
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 08:00:15
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 08:39:17
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:33:59
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	25 Aug 2020 19:08:55

US3522082

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:00:15

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 08:39:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:33:59
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	25 Aug 2020 19:08:55

US3522082

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:00:15

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 08:39:17
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:33:59
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	25 Aug 2020 19:08:55

US3522082

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:00:15

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:33:59
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	25 Aug 2020 19:08:55

US3522082

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:00:15

Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:33:59
User entered empty.	Sharon Mathys (b) (4) (b) (4)	25 Aug 2020 19:08:55

US3522082

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:00:15

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
User entered '1'	Sharon Mathys (b) (4) (b) (4)	25 Aug 2020 19:08:55

US3522082

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:00:15

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:33:59
User entered '0'	Sharon Mathys (b) (4) (b) (4)	25 Aug 2020 19:08:55

US3522082

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:00:15

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 08:39:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:33:59
User entered '0'	Sharon Mathys (b) (4) (b) (4)	25 Aug 2020 19:08:55

Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 08:00:15
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 08:39:17
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:33:59
User entered '0'	Sharon Mathys (b) (4)	25 Aug 2020 19:08:55

US3522082

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:00:15

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 08:39:17
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:33:59
User entered '0'	Sharon Mathys (b) (4) (b) (4)	25 Aug 2020 19:08:55

US3522082

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:00:15

Resides in a single family home (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:33:59
User entered '0'	Sharon Mathys (b) (4) (b) (4)	25 Aug 2020 19:08:55

US3522082

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:00:15

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
User entered '0'	Sharon Mathys (b) (4) (b) (4)	25 Aug 2020 19:08:55

US3522082
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 08:00:15
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:39:17
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:33:59
User entered empty.	Sharon Mathys (b) (4) (b) (4)	25 Aug 2020 19:08:55

US3522082

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:00:15

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:34:38
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:34:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 17:30:53

US3522082

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:00:15

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:34:38
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:34:05
User entered '11 Aug 2020'	(b) (4), (b) (6)	11 Aug 2020 17:30:53

US3522082

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:00:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:34:38
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:34:05
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	11 Aug 2020 17:30:53

US3522082
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 10 Jun 2021 08:00:15
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:34:38
User entered 'VISIT1'	System	11 Aug 2020 17:30:53

US3522082

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:00:15

What was the date of randomization? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:34:38
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:34:12
User entered '11 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	11 Aug 2020 17:09:45

US3522082
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 08:00:15

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:34:38
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:34:12
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 03:36:30
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:36:30
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	11 Aug 2020 17:09:45
User entered '103004' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	11 Aug 2020 17:09:45

US3522082

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:00:15

In what Cohort was the participant enrolled?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:34:38
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:34:12
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	11 Aug 2020 17:09:45

US3522082

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:00:15

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)	03 Apr 2021 03:34:38
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:34:12
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 17:36:46

US3522082

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:00:15

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)	03 Apr 2021 03:34:38
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 17:06:52
Query 'Significant cardiac disease is recorded as Yes, but Cohort group is not recorded as 'at risk'. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	08 Dec 2020 00:22:21
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:34:12
User opened query 'Significant cardiac disease is recorded as Yes, but Cohort group is not recorded as 'at risk'. Please review and reconcile.' (Site from System).	System	11 Aug 2020 17:36:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 17:36:46

US3522082

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:00:15

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:34:38
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:34:12
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 17:36:46

US3522082

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:00:15

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:34:38
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:34:12
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 17:36:46

US3522082

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:00:15

Liver Disease

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:34:38
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:34:12
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 17:36:46

US3522082

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:00:15

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:34:38
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:34:31
User entered missing code ND - Not Done; reason for change Data Entry Error	Sharon Mathys (b) (4)	13 Aug 2020 18:15:22
User entered '66.5' in	(b) (4), (b) (6)	11 Aug 2020 17:43:01

US3522082

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:00:15

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:34:38
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:34:32
User entered missing code ND - Not Done; reason for change Data Entry Error	Sharon Mathys (b) (4) (b) (4)	13 Aug 2020 18:15:22
User entered '155.7' lb	(b) (4), (b) (6)	11 Aug 2020 17:43:01

US3522082
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 08:00:15
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:34:38
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:34:31
User entered missing code ND - Not Done; reason for change Data Entry Error	Sharon Mathys (b) (4) (b) (4)	13 Aug 2020 18:15:22
User entered '66.5' in	(b) (4), (b) (6)	11 Aug 2020 17:43:01

US3522082
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 08:00:15

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:34:38
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:34:32
User entered missing code ND - Not Done; reason for change Data Entry Error	Sharon Mathys (b) (4)	13 Aug 2020 18:15:22
User entered '155.7' lb	(b) (4), (b) (6)	11 Aug 2020 17:43:01

US3522082
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 08:00:15
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:34:38
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	11 Aug 2020 17:43:01

US3522082

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:00:15

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:34:38
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:34:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 17:43:01

US3522082

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:00:15

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:34:38
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:35:00
User entered '11 Aug 2020'	(b) (4), (b) (6)	11 Aug 2020 17:43:01

US3522082

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:00:15

Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:34:38
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:35:02
User entered '13:30'	(b) (4), (b) (6)	11 Aug 2020 17:43:01

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:34:38
User entered '11 Aug 2020 13:30'	System	11 Aug 2020 17:43:01

US3522082

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:00:15

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:34:38
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 17:06:52
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	18 Sep 2020 06:48:45
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	Sharon Mathys (b) (4) (b) (4)	17 Sep 2020 13:10:38
Amendment Manager: User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	16 Sep 2020 23:51:54
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:35:03
User entered '96.4' F	(b) (4), (b) (6)	11 Aug 2020 17:43:01

US3522082

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:00:15

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:34:38
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:35:05
User entered 'Other (Other)'	(b) (4), (b) (6)	11 Aug 2020 17:43:01

US3522082

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:00:15

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:34:38
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4), (b) (6)	13 Sep 2020 22:18:44
User closed query 'For research purposes please spell this out as infrared.' (Site from CRA).	(b) (4), (b) (6)	13 Sep 2020 22:18:40
Query 'For research purposes please spell this out as infrared.' answered with 'was temporal, changing to match source' (Site from CRA).	Sharon Mathys (b) (4) (b) (4)	09 Sep 2020 14:18:58
User entered 'Temporal' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	09 Sep 2020 14:18:45
User opened query 'For research purposes please spell this out as infrared.' (Site from CRA).	(b) (4), (b) (6)	09 Sep 2020 13:35:28
User entered 'IR'	(b) (4), (b) (6)	11 Aug 2020 17:43:01

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:34:38
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:35:32
User entered '70'	(b) (4), (b) (6)	11 Aug 2020 17:43:01

US3522082

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:00:15

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:34:38
User entered 'bpm'	System	11 Aug 2020 17:43:01

US3522082

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:00:15

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:34:38
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:35:35
User entered '18'	(b) (4), (b) (6)	11 Aug 2020 17:43:01

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:34:38
User entered 'breaths/min'	System	11 Aug 2020 17:43:01

US3522082

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:00:15

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:34:38
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:35:37
User entered '98'	(b) (4), (b) (6)	11 Aug 2020 17:43:01

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:34:38
User entered 'mmHg'	System	11 Aug 2020 17:43:01

US3522082

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:00:15

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:34:38
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:35:39
User entered '67'	(b) (4), (b) (6)	11 Aug 2020 17:43:01

US3522082

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:00:15

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:34:38
User entered 'mmHg'	System	11 Aug 2020 17:43:01

US3522082

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:00:15

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:34:38
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:34:31
User entered missing code ND - Not Done; reason for change Data Entry Error	Sharon Mathys (b) (4)	13 Aug 2020 18:15:22
User entered '66.5' in	(b) (4), (b) (6)	11 Aug 2020 17:43:01

US3522082

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:00:15

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:34:38
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:34:32
User entered missing code ND - Not Done; reason for change Data Entry Error	Sharon Mathys (b) (4)	13 Aug 2020 18:15:22
User entered '155.7' lb	(b) (4), (b) (6)	11 Aug 2020 17:43:01

US3522082

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:00:15

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:34:38
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	11 Aug 2020 17:43:01

US3522082

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:00:15

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:34:38
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:35:54
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Aug 2020 19:25:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Aug 2020 19:25:55
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Aug 2020 19:25:55
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Aug 2020 17:43:01
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 17:43:01

US3522082

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:00:15

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:34:38
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:35:56
User entered '11 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Aug 2020 19:25:55
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 17:43:01

US3522082

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:00:15

Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:34:38
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:36:17
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	17 Aug 2020 14:59:01
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	11 Aug 2020 19:26:07
User closed query 'Data is required. Please provide.' (Site from System).	System	11 Aug 2020 19:26:07
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	11 Aug 2020 19:26:07
User entered '15:25' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Aug 2020 19:26:07
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Aug 2020 19:25:55
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 17:43:01

US3522082

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:00:15

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:34:38
User entered '11 Aug 2020 15:25'	System	11 Aug 2020 19:26:07
User entered empty.	System	11 Aug 2020 17:43:01

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:34:38
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:36:28
User entered '97.4' F reason for change: Data Entry Error	(b) (4), (b) (6)	11 Aug 2020 19:25:55
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 17:43:01

US3522082

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:00:15

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:34:38
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:36:30
User entered 'Other (Other)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Aug 2020 19:25:55
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 17:43:01

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:34:38
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4), (b) (6)	13 Sep 2020 22:19:12
User closed query 'For research purpose please spell this out as infrared.' (Site from CRA).	(b) (4), (b) (6)	13 Sep 2020 22:19:09
Query 'For research purpose please spell this out as infrared.' answered with 'was temporal, changing to match source' (Site from CRA).	Sharon Mathys (b) (4)	09 Sep 2020 14:19:41
User entered 'Temporal' reason for change: Data Entry Error	Sharon Mathys (b) (4)	09 Sep 2020 14:19:15
User opened query 'For research purpose please spell this out as infrared.' (Site from CRA).	(b) (4), (b) (6)	09 Sep 2020 13:36:51
User entered 'IR' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Aug 2020 19:25:55
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 17:43:01

US3522082

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:00:15

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:34:38
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:36:54
User entered '65' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Aug 2020 19:25:55
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 17:43:01

Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 08:00:15
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:34:38
User entered 'bpm'	System	11 Aug 2020 19:25:55
User entered empty.	System	11 Aug 2020 17:43:01

US3522082

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:00:15

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:34:38
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:36:57
User entered '16' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Aug 2020 19:25:55
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 17:43:01

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:34:38
User entered 'breaths/min'	System	11 Aug 2020 19:25:55
User entered empty.	System	11 Aug 2020 17:43:01

US3522082

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:00:15

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:34:38
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:37:00
User entered '111' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Aug 2020 19:25:55
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 17:43:01

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:34:38
User entered 'mmHg'	System	11 Aug 2020 19:25:55
User entered empty.	System	11 Aug 2020 17:43:01

US3522082

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:00:15

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:34:38
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:37:02
User entered '70' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Aug 2020 19:25:55
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 17:43:01

US3522082

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:00:15

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:34:38
User entered 'mmHg'	System	11 Aug 2020 19:25:55
User entered empty.	System	11 Aug 2020 17:43:01

US3522082

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:00:15

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:34:38
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:39:03
User entered 'No (N)' reason for change: Data Entry Error	Sharon Mathys (b) (4)	17 Aug 2020 15:56:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 17:43:13

US3522082

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:00:15

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:34:38
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:39:03
User entered empty; reason for change Data Entry Error	Sharon Mathys (b) (4)	17 Aug 2020 15:56:03
User entered '11 Aug 2020'	(b) (4), (b) (6)	11 Aug 2020 17:43:13

US3522082
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 08:00:15
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:34:38
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:39:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 19:01:01

US3522082

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:00:15

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:34:38
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:39:51
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 19:01:01

US3522082

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:00:15

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)	03 Apr 2021 03:34:38
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:39:51
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 19:01:01

US3522082
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 08:00:15
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:34:38
User entered 'MRNA-1273 OR PLACEBO'	System	11 Aug 2020 19:01:01

US3522082

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:00:15

What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:34:38
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:39:44
User entered '11 Aug 2020'	(b) (4), (b) (6)	11 Aug 2020 19:01:01

US3522082

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:00:15

What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:34:38
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:39:45
User entered '14:57'	(b) (4), (b) (6)	11 Aug 2020 19:01:01

US3522082
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 08:00:15
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:34:38
User entered '11 Aug 2020 14:57'	System	11 Aug 2020 19:01:01

US3522082

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:00:15

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:34:38
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:39:46
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	11 Aug 2020 19:01:01

US3522082
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 08:00:15

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:34:38
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:39:47
User entered 'ONCE'	System	11 Aug 2020 19:01:01

US3522082
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 08:00:15
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:34:38
User entered 'INTRAMUSCULAR'	System	11 Aug 2020 19:01:01

US3522082

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:00:15

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:34:38
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:41:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 18:27:41

US3522082

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:00:15

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:34:38
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:41:09
User entered '11 Aug 2020'	(b) (4), (b) (6)	11 Aug 2020 18:27:41

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:34:38
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:41:09
User entered '14:15'	(b) (4), (b) (6)	11 Aug 2020 18:27:41

US3522082

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:00:15

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:34:38
User entered '11 Aug 2020 14:15'	System	11 Aug 2020 18:27:41

US3522082

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:00:15

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:34:38
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:41:13
User entered '11 Aug 2020'	(b) (4), (b) (6)	11 Aug 2020 18:28:04

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:34:38
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	11 Aug 2020 18:28:04

US3522082

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:00:15

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:34:38
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:41:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 18:28:04

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:34:38
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:41:13
User entered '14:17'	(b) (4), (b) (6)	11 Aug 2020 18:28:04

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:34:38
User entered '11 Aug 2020 14:17'	System	11 Aug 2020 18:28:04

US3522082

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:00:15

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:34:38
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	11 Aug 2020 18:28:04

US3522082

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:00:15

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:34:38
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:41:13
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 18:28:04

US3522082

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:00:15

Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:34:38
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:41:13
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 18:28:04

US3522082

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:00:15

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:34:38
User entered empty.	System	11 Aug 2020 18:28:04

US3522082

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:00:15

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:34:38
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:41:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 17:43:20

US3522082
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 10 Jun 2021 08:00:15
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:34:38
User entered '1'	System	11 Aug 2020 17:43:20

US3522082
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
Data entry locked.	System	11 Aug 2020 19:01:01
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 19:01:01

US3522082

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:00:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-11T15:19:27', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'c78950fa-d240-483f-ac78-035b9ffa37a4'	System	11 Aug 2020 19:19:56
User entered 'Yes (Y)'	System	11 Aug 2020 19:19:56

US3522082

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:00:15

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-11T15:19:39', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'c78950fa-d240-483f-ac78-035b9ffa37a4'	System	11 Aug 2020 19:19:56
User entered '97.4'	System	11 Aug 2020 19:19:56

US3522082

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:00:15

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-11T15:19:46', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'c78950fa-d240-483f-ac78-035b9ffa37a4'	System	11 Aug 2020 19:19:56
User entered 'No (N)'	System	11 Aug 2020 19:19:56

US3522082

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:00:15

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-11T15:19:52', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'c78950fa-d240-483f-ac78-035b9ffa37a4'	System	11 Aug 2020 19:19:56
User entered '11 Aug 2020 15:19'	System	11 Aug 2020 19:19:56

US3522082

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:00:15

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
User entered '11 Aug 2020 15:17'	System	11 Aug 2020 19:01:01

US3522082

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:00:15

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
User entered '11 Aug 2020 17:47'	System	11 Aug 2020 19:01:01

US3522082
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
Data entry locked.	System	11 Aug 2020 19:01:01
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 19:01:01

US3522082

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:00:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-11T18:50:18', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'edd0b942-e19e-477c-9242-8bd4687dab32'	System	11 Aug 2020 22:51:15
User entered 'Yes (Y)'	System	11 Aug 2020 22:51:15

US3522082

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:00:15

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-11T18:50:32', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'edd0b942-e19e-477c-9242-8bd4687dab32'	System	11 Aug 2020 22:51:15
User entered '97.3'	System	11 Aug 2020 22:51:15

US3522082

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:00:15

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-11T18:50:39', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'edd0b942-e19e-477c-9242-8bd4687dab32'	System	11 Aug 2020 22:51:15
User entered 'No (N)'	System	11 Aug 2020 22:51:15

US3522082

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:00:15

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-11T18:51:11', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'edd0b942-e19e-477c-9242-8bd4687dab32'	System	11 Aug 2020 22:51:15
User entered '11 Aug 2020 18:51'	System	11 Aug 2020 22:51:15

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
User entered '11 Aug 2020 18:42'	System	11 Aug 2020 19:01:01

Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 08:00:15
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 19:01:01

US3522082
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
Data entry locked.	System	11 Aug 2020 19:01:01
User entered 'Day 2'	System	11 Aug 2020 19:01:01

US3522082

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:00:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-12T12:02:54', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '9d1a0abd-2bb0-4c39-b049-b87d28275a02'	System	12 Aug 2020 16:03:54
User entered 'Yes (Y)'	System	12 Aug 2020 16:03:54

US3522082
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 08:00:15

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-12T12:03:35', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '9d1a0abd-2bb0-4c39-b049-b87d28275a02'	System	12 Aug 2020 16:03:54
User entered '96.3'	System	12 Aug 2020 16:03:54

US3522082

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:00:15

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-12T12:03:42', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '9d1a0abd-2bb0-4c39-b049-b87d28275a02'	System	12 Aug 2020 16:03:54
User entered 'No (N)'	System	12 Aug 2020 16:03:54

US3522082
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 08:00:15
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-12T12:03:50', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '9d1a0abd-2bb0-4c39-b049-b87d28275a02'	System	12 Aug 2020 16:03:54
User entered '12 Aug 2020 12:03'	System	12 Aug 2020 16:03:54

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 19:01:01

US3522082
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 08:00:15
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 19:01:01

US3522082
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
Data entry locked.	System	11 Aug 2020 19:01:01
User entered 'Day 3'	System	11 Aug 2020 19:01:01

US3522082

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:00:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-13T12:15:01', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '44904398-48ca-462b-8105-f47a98dce407'	System	13 Aug 2020 16:15:36
User entered 'Yes (Y)'	System	13 Aug 2020 16:15:36

US3522082

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:00:15

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-13T12:15:15', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '44904398-48ca-462b-8105-f47a98dce407'	System	13 Aug 2020 16:15:36
User entered '97.3'	System	13 Aug 2020 16:15:36

US3522082

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:00:15

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-13T12:15:21', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '44904398-48ca-462b-8105-f47a98dce407'	System	13 Aug 2020 16:15:36
User entered 'No (N)'	System	13 Aug 2020 16:15:36

US3522082

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:00:15

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-13T12:15:29', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '44904398-48ca-462b-8105-f47a98dce407'	System	13 Aug 2020 16:15:36
User entered '13 Aug 2020 12:15'	System	13 Aug 2020 16:15:36

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 19:01:01

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US3522082

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:00:15

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 19:01:01

US3522082
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
Data entry locked.	System	11 Aug 2020 19:01:01
User entered 'Day 4'	System	11 Aug 2020 19:01:01

US3522082

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:00:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-14T17:27:31', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'af219faf-6bfc-4c08-8a43-fcf6e84b4605'	System	14 Aug 2020 21:27:57
User entered 'Yes (Y)'	System	14 Aug 2020 21:27:57

US3522082

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:00:15

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-14T17:27:38', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'af219faf-6bfc-4c08-8a43-fcf6e84b4605'	System	14 Aug 2020 21:27:57
User entered '97.3'	System	14 Aug 2020 21:27:57

US3522082

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:00:15

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-14T17:27:44', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'af219faf-6bfc-4c08-8a43-fcf6e84b4605'	System	14 Aug 2020 21:27:57
User entered 'No (N)'	System	14 Aug 2020 21:27:57

US3522082

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:00:15

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-14T17:27:53', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'af219faf-6bfc-4c08-8a43-fcf6e84b4605'	System	14 Aug 2020 21:27:57
User entered '14 Aug 2020 17:27'	System	14 Aug 2020 21:27:57

US3522082

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:00:15

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 19:01:01

US3522082
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 08:00:15
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 19:01:01

US3522082
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
Data entry locked.	System	11 Aug 2020 19:01:01
User entered 'Day 5'	System	11 Aug 2020 19:01:01

US3522082

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:00:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-15T12:57:10', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '3faa3532-eb5f-465e-b862-08db4ebf3b99'	System	15 Aug 2020 17:01:13
User entered 'Yes (Y)'	System	15 Aug 2020 17:01:13

US3522082

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:00:15

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-15T13:00:57', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '3faa3532-eb5f-465e-b862-08db4ebf3b99'	System	15 Aug 2020 17:01:13
User entered '95.9'	System	15 Aug 2020 17:01:13

US3522082

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:00:15

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-15T13:01:02', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '3faa3532-eb5f-465e-b862-08db4ebf3b99'	System	15 Aug 2020 17:01:13
User entered 'No (N)'	System	15 Aug 2020 17:01:13

US3522082

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:00:15

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-15T13:01:10', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '3faa3532-eb5f-465e-b862-08db4ebf3b99'	System	15 Aug 2020 17:01:13
User entered '15 Aug 2020 13:01'	System	15 Aug 2020 17:01:13

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 19:01:01

US3522082

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:00:15

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 19:01:01

US3522082
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
Data entry locked.	System	11 Aug 2020 19:01:01
User entered 'Day 6'	System	11 Aug 2020 19:01:01

US3522082

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:00:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-16T19:31:20', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'fb6c3644-4996-42d4-b9b4-fb7568d301d4'	System	16 Aug 2020 23:31:46
User entered 'Yes (Y)'	System	16 Aug 2020 23:31:46

US3522082

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:00:15

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-16T19:31:27', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'fb6c3644-4996-42d4-b9b4-fb7568d301d4'	System	16 Aug 2020 23:31:46
User entered '97.3'	System	16 Aug 2020 23:31:46

US3522082

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:00:15

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-16T19:31:33', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'fb6c3644-4996-42d4-b9b4-fb7568d301d4'	System	16 Aug 2020 23:31:46
User entered 'No (N)'	System	16 Aug 2020 23:31:46

US3522082
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 08:00:15
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-16T19:31:42', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'fb6c3644-4996-42d4-b9b4-fb7568d301d4'	System	16 Aug 2020 23:31:46
User entered '16 Aug 2020 19:31'	System	16 Aug 2020 23:31:46

US3522082
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 08:00:15
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 19:01:01

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 19:01:01

FDA-CBER-2022-1614-0811939

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
Data entry locked.	System	11 Aug 2020 19:01:01
User entered 'Day 7'	System	11 Aug 2020 19:01:01

US3522082

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:00:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-17T19:04:10', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '870b2eb0-0957-41b7-a6d5-173a6fbc6b65'	System	17 Aug 2020 23:05:12
User entered 'Yes (Y)'	System	17 Aug 2020 23:05:12

US3522082

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:00:15

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-17T19:04:57', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '870b2eb0-0957-41b7-a6d5-173a6fbc6b65'	System	17 Aug 2020 23:05:12
User entered '96.6'	System	17 Aug 2020 23:05:12

US3522082

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:00:15

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-17T19:05:04', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '870b2eb0-0957-41b7-a6d5-173a6fbc6b65'	System	17 Aug 2020 23:05:12
User entered 'No (N)'	System	17 Aug 2020 23:05:12

US3522082

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:00:15

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-17T19:05:09', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '870b2eb0-0957-41b7-a6d5-173a6fbc6b65'	System	17 Aug 2020 23:05:12
User entered '17 Aug 2020 19:05'	System	17 Aug 2020 23:05:12

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 19:01:01

US3522082

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:00:15

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 19:01:01

US3522082
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
Data entry locked.	System	11 Aug 2020 19:01:01
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 19:01:01

US3522082

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:00:15

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 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-11T15:20:20', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '3b1c962b-3cb0-43df-bf4c-f8e1b1ec54ba'	System	11 Aug 2020 19:20:56
User entered 'None (1)'	System	11 Aug 2020 19:20:56

US3522082

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:00:15

Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-11T15:20:34', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '3b1c962b-3cb0-43df-bf4c-f8e1b1ec54ba'	System	11 Aug 2020 19:20:56
User entered 'No (N)'	System	11 Aug 2020 19:20:56

US3522082

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:00:15

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-11T15:20:42', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '3b1c962b-3cb0-43df-bf4c-f8e1b1ec54ba'	System	11 Aug 2020 19:20:56
User entered 'No (N)'	System	11 Aug 2020 19:20:56

US3522082

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:00:15

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 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-11T15:20:48', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '3b1c962b-3cb0-43df-bf4c-f8e1b1ec54ba'	System	11 Aug 2020 19:20:56
User entered 'None (1)'	System	11 Aug 2020 19:20:56

US3522082
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 08:00:15
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-11T15:20:53', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '3b1c962b-3cb0-43df-bf4c-f8e1b1ec54ba'	System	11 Aug 2020 19:20:56
User entered '11 Aug 2020 15:20'	System	11 Aug 2020 19:20:56

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
User entered '11 Aug 2020 15:17'	System	11 Aug 2020 19:01:01

FDA-CBER-2022-1614-0811953

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
User entered '11 Aug 2020 17:47'	System	11 Aug 2020 19:01:01

US3522082
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
Data entry locked.	System	11 Aug 2020 19:01:01
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 19:01:01

US3522082

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:00:15

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 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-11T18:52:05', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'fe132274-5c53-4dbe-b7f7-04f7ddf81033'	System	11 Aug 2020 22:52:54
User entered 'None (1)'	System	11 Aug 2020 22:52:54

US3522082

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:00:15

Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-11T18:52:11', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'fe132274-5c53-4dbe-b7f7-04f7ddf81033'	System	11 Aug 2020 22:52:54
User entered 'No (N)'	System	11 Aug 2020 22:52:54

US3522082

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:00:15

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-11T18:52:15', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'fe132274-5c53-4dbe-b7f7-04f7ddf81033'	System	11 Aug 2020 22:52:54
User entered 'No (N)'	System	11 Aug 2020 22:52:54

FDA-CBER-2022-1614-0811958

US3522082

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:00:15

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 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-11T18:52:28', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'fe132274-5c53-4dbe-b7f7-04f7ddf81033'	System	11 Aug 2020 22:52:54
User entered 'None (1)'	System	11 Aug 2020 22:52:54

US3522082

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:00:15

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-11T18:52:51', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'fe132274-5c53-4dbe-b7f7-04f7ddf81033'	System	11 Aug 2020 22:52:54
User entered '11 Aug 2020 18:52'	System	11 Aug 2020 22:52:54

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
User entered '11 Aug 2020 18:42'	System	11 Aug 2020 19:01:01

US3522082
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 08:00:15
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 19:01:01

US3522082
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
Data entry locked.	System	11 Aug 2020 19:01:01
User entered 'Day 2'	System	11 Aug 2020 19:01:01

US3522082

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:00:15

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 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-12T12:05:51', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '948532ea-20da-4f46-a4a1-a987e420dd10'	System	12 Aug 2020 16:06:26
User entered 'Does not interfere with activity (2)'	System	12 Aug 2020 16:06:26

US3522082

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:00:15

Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-12T12:05:56', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '948532ea-20da-4f46-a4a1-a987e420dd10'	System	12 Aug 2020 16:06:26
User entered 'No (N)'	System	12 Aug 2020 16:06:26

US3522082

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:00:15

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-12T12:06:13', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '948532ea-20da-4f46-a4a1-a987e420dd10'	System	12 Aug 2020 16:06:26
User entered 'No (N)'	System	12 Aug 2020 16:06:26

US3522082

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:00:15

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 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-12T12:06:19', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '948532ea-20da-4f46-a4a1-a987e420dd10'	System	12 Aug 2020 16:06:26
User entered 'None (1)'	System	12 Aug 2020 16:06:26

US3522082

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:00:15

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-12T12:06:23', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '948532ea-20da-4f46-a4a1-a987e420dd10'	System	12 Aug 2020 16:06:26
User entered '12 Aug 2020 12:06'	System	12 Aug 2020 16:06:26

US3522082

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:00:15

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 19:01:01

US3522082
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 08:00:15
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 19:01:01

US3522082
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
Data entry locked.	System	11 Aug 2020 19:01:01
User entered 'Day 3'	System	11 Aug 2020 19:01:01

US3522082

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:00:15

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 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-13T12:15:42', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'fd189379-9a7e-41b4-9ba9-c39886650963'	System	13 Aug 2020 16:16:18
User entered 'None (1)'	System	13 Aug 2020 16:16:18

US3522082

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:00:15

Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-13T12:15:47', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'fd189379-9a7e-41b4-9ba9-c39886650963'	System	13 Aug 2020 16:16:18
User entered 'No (N)'	System	13 Aug 2020 16:16:18

US3522082

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:00:15

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-13T12:15:52', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'fd189379-9a7e-41b4-9ba9-c39886650963'	System	13 Aug 2020 16:16:18
User entered 'No (N)'	System	13 Aug 2020 16:16:18

US3522082

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:00:15

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 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-13T12:16:00', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'fd189379-9a7e-41b4-9ba9-c39886650963'	System	13 Aug 2020 16:16:18
User entered 'None (1)'	System	13 Aug 2020 16:16:18

US3522082
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 08:00:15
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-13T12:16:12', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'fd189379-9a7e-41b4-9ba9-c39886650963'	System	13 Aug 2020 16:16:18
User entered '13 Aug 2020 12:16'	System	13 Aug 2020 16:16:18

US3522082
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 08:00:15

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 19:01:01

US3522082

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:00:15

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 19:01:01

US3522082

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:00:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
Data entry locked.	System	11 Aug 2020 19:01:01
User entered 'Day 4'	System	11 Aug 2020 19:01:01

US3522082

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:00:15

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 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-14T17:28:06', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '0be91760-f3c4-4b07-9e6b-4d9b76d10070'	System	14 Aug 2020 21:28:35
User entered 'None (1)'	System	14 Aug 2020 21:28:35

US3522082

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:00:15

Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-14T17:28:11', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '0be91760-f3c4-4b07-9e6b-4d9b76d10070'	System	14 Aug 2020 21:28:35
User entered 'No (N)'	System	14 Aug 2020 21:28:35

FDA-CBER-2022-1614-0811981

US3522082

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:00:15

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-14T17:28:16', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '0be91760-f3c4-4b07-9e6b-4d9b76d10070'	System	14 Aug 2020 21:28:35
User entered 'No (N)'	System	14 Aug 2020 21:28:35

US3522082

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:00:15

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 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-14T17:28:20', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '0be91760-f3c4-4b07-9e6b-4d9b76d10070'	System	14 Aug 2020 21:28:35
User entered 'None (1)'	System	14 Aug 2020 21:28:35

US3522082
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 08:00:15
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-14T17:28:28', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '0be91760-f3c4-4b07-9e6b-4d9b76d10070'	System	14 Aug 2020 21:28:35
User entered '14 Aug 2020 17:28'	System	14 Aug 2020 21:28:35

US3522082
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 08:00:15
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 19:01:01

US3522082

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:00:15

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 19:01:01

US3522082
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
Data entry locked.	System	11 Aug 2020 19:01:01
User entered 'Day 5'	System	11 Aug 2020 19:01:01

US3522082

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:00:15

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 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-15T13:01:22', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '2f14fc78-b3c1-4151-9b8e-0f860d23b2f1'	System	15 Aug 2020 17:01:45
User entered 'None (1)'	System	15 Aug 2020 17:01:45

US3522082

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:00:15

Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-15T13:01:27', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '2f14fc78-b3c1-4151-9b8e-0f860d23b2f1'	System	15 Aug 2020 17:01:45
User entered 'No (N)'	System	15 Aug 2020 17:01:45

US3522082

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:00:15

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-15T13:01:30', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '2f14fc78-b3c1-4151-9b8e-0f860d23b2f1'	System	15 Aug 2020 17:01:45
User entered 'No (N)'	System	15 Aug 2020 17:01:45

FDA-CBER-2022-1614-0811990

US3522082

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:00:15

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 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-15T13:01:34', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '2f14fc78-b3c1-4151-9b8e-0f860d23b2f1'	System	15 Aug 2020 17:01:45
User entered 'None (1)'	System	15 Aug 2020 17:01:45

US3522082

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:00:15

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-15T13:01:42', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '2f14fc78-b3c1-4151-9b8e-0f860d23b2f1'	System	15 Aug 2020 17:01:45
User entered '15 Aug 2020 13:01'	System	15 Aug 2020 17:01:45

US3522082
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 08:00:15
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 19:01:01

US3522082
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 08:00:15
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 19:01:01

US3522082
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
Data entry locked.	System	11 Aug 2020 19:01:01
User entered 'Day 6'	System	11 Aug 2020 19:01:01

US3522082

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:00:15

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 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-16T19:32:00', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'e69ab253-74b0-4b10-a4ce-12954823aa41'	System	16 Aug 2020 23:32:17
User entered 'None (1)'	System	16 Aug 2020 23:32:17

US3522082

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:00:15

Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-16T19:32:03', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'e69ab253-74b0-4b10-a4ce-12954823aa41'	System	16 Aug 2020 23:32:17
User entered 'No (N)'	System	16 Aug 2020 23:32:17

US3522082

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:00:15

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-16T19:32:06', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'e69ab253-74b0-4b10-a4ce-12954823aa41'	System	16 Aug 2020 23:32:17
User entered 'No (N)'	System	16 Aug 2020 23:32:17

US3522082

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:00:15

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 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-16T19:32:10', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'e69ab253-74b0-4b10-a4ce-12954823aa41'	System	16 Aug 2020 23:32:17
User entered 'None (1)'	System	16 Aug 2020 23:32:17

US3522082
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 08:00:15
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-16T19:32:14', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'e69ab253-74b0-4b10-a4ce-12954823aa41'	System	16 Aug 2020 23:32:17
User entered '16 Aug 2020 19:32'	System	16 Aug 2020 23:32:17

US3522082
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 08:00:15

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 19:01:01

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 19:01:01

FDA-CBER-2022-1614-0812002

Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
Data entry locked.	System	11 Aug 2020 19:01:01
User entered 'Day 7'	System	11 Aug 2020 19:01:01

US3522082

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:00:15

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 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-17T17:59:42', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '975fdb37-85ce-462f-add8-1c8922294f72'	System	17 Aug 2020 22:00:12
User entered 'None (1)'	System	17 Aug 2020 22:00:12

US3522082

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:00:15

Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-17T17:59:48', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '975fdb37-85ce-462f-add8-1c8922294f72'	System	17 Aug 2020 22:00:12
User entered 'No (N)'	System	17 Aug 2020 22:00:12

US3522082

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:00:15

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-17T17:59:54', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '975fdb37-85ce-462f-add8-1c8922294f72'	System	17 Aug 2020 22:00:12
User entered 'No (N)'	System	17 Aug 2020 22:00:12

US3522082

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:00:15

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 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-17T18:00:02', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '975fdb37-85ce-462f-add8-1c8922294f72'	System	17 Aug 2020 22:00:12
User entered 'None (1)'	System	17 Aug 2020 22:00:12

US3522082
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 08:00:15
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-17T18:00:07', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '975fdb37-85ce-462f-add8-1c8922294f72'	System	17 Aug 2020 22:00:12
User entered '17 Aug 2020 18:00'	System	17 Aug 2020 22:00:12

US3522082

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:00:15

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 19:01:01

US3522082
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 08:00:15
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 19:01:01

US3522082
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
Data entry locked.	System	11 Aug 2020 19:01:01
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 19:01:01

US3522082
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 08:00:15
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-11T15:21:06', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '278e0974-c563-4a08-9a2c-d424cb3bc2a5'	System	11 Aug 2020 19:21:42
User entered 'None (0)'	System	11 Aug 2020 19:21:42

US3522082
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 08:00:15
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-11T15:21:10', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '278e0974-c563-4a08-9a2c-d424cb3bc2a5'	System	11 Aug 2020 19:21:42
User entered 'None (0)'	System	11 Aug 2020 19:21:42

US3522082
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 08:00:15
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-11T15:21:14', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '278e0974-c563-4a08-9a2c-d424cb3bc2a5'	System	11 Aug 2020 19:21:42
User entered 'None (0)'	System	11 Aug 2020 19:21:42

US3522082

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:00:15

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-11T15:21:16', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '278e0974-c563-4a08-9a2c-d424cb3bc2a5'	System	11 Aug 2020 19:21:42
User entered 'None (0)'	System	11 Aug 2020 19:21:42

US3522082

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:00:15

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-11T15:21:19', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '278e0974-c563-4a08-9a2c-d424cb3bc2a5'	System	11 Aug 2020 19:21:42
User entered 'None (0)'	System	11 Aug 2020 19:21:42

US3522082
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 08:00:15
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-11T15:21:22', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '278e0974-c563-4a08-9a2c-d424cb3bc2a5'	System	11 Aug 2020 19:21:42
User entered 'None (0)'	System	11 Aug 2020 19:21:42

US3522082

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:00:15

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 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-11T15:21:31', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '278e0974-c563-4a08-9a2c-d424cb3bc2a5'	System	11 Aug 2020 19:21:42
User entered 'No (N)'	System	11 Aug 2020 19:21:42

US3522082

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:00:15

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-11T15:21:37', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '278e0974-c563-4a08-9a2c-d424cb3bc2a5'	System	11 Aug 2020 19:21:42
User entered '11 Aug 2020 15:21'	System	11 Aug 2020 19:21:42

US3522082

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:00:15

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
User entered '11 Aug 2020 15:17'	System	11 Aug 2020 19:01:01

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
User entered '11 Aug 2020 17:47'	System	11 Aug 2020 19:01:01

US3522082
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
Data entry locked.	System	11 Aug 2020 19:01:01
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 19:01:01

US3522082
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 08:00:15
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-11T18:51:21', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'cfc0ffc0-f247-414c-9100-d7588f99d923'	System	11 Aug 2020 22:51:58
User entered 'None (0)'	System	11 Aug 2020 22:51:58

US3522082
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 08:00:15
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-11T18:51:25', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'cfc0ffc0-f247-414c-9100-d7588f99d923'	System	11 Aug 2020 22:51:58
User entered 'None (0)'	System	11 Aug 2020 22:51:58

US3522082
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 08:00:15
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-11T18:51:29', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'cfc0ffc0-f247-414c-9100-d7588f99d923'	System	11 Aug 2020 22:51:58
User entered 'None (0)'	System	11 Aug 2020 22:51:58

US3522082

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:00:15

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-11T18:51:32', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'cfc0ffc0-f247-414c-9100-d7588f99d923'	System	11 Aug 2020 22:51:58
User entered 'None (0)'	System	11 Aug 2020 22:51:58

US3522082
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 08:00:15
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-11T18:51:36', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'cfc0ffc0-f247-414c-9100-d7588f99d923'	System	11 Aug 2020 22:51:58
User entered 'None (0)'	System	11 Aug 2020 22:51:58

US3522082
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 08:00:15
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-11T18:51:38', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'cfc0ffc0-f247-414c-9100-d7588f99d923'	System	11 Aug 2020 22:51:58
User entered 'None (0)'	System	11 Aug 2020 22:51:58

US3522082

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:00:15

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 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-11T18:51:44', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'cfc0ffc0-f247-414c-9100-d7588f99d923'	System	11 Aug 2020 22:51:58
User entered 'No (N)'	System	11 Aug 2020 22:51:58

US3522082
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 08:00:15
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-11T18:51:55', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'cfc0ffc0-f247-414c-9100-d7588f99d923'	System	11 Aug 2020 22:51:58
User entered '11 Aug 2020 18:51'	System	11 Aug 2020 22:51:58

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
User entered '11 Aug 2020 18:42'	System	11 Aug 2020 19:01:01

FDA-CBER-2022-1614-0812031

US3522082

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:00:15

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 19:01:01

US3522082
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
Data entry locked.	System	11 Aug 2020 19:01:01
User entered 'Day 2'	System	11 Aug 2020 19:01:01

US3522082
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 08:00:15
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-12T12:04:08', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'a8fa7898-0e16-4b03-8a54-4409e2224d4d'	System	12 Aug 2020 16:05:22
User entered 'None (0)'	System	12 Aug 2020 16:05:22

US3522082
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 08:00:15
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-12T12:04:12', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'a8fa7898-0e16-4b03-8a54-4409e2224d4d'	System	12 Aug 2020 16:05:22
User entered 'None (0)'	System	12 Aug 2020 16:05:22

US3522082

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:00:15

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-12T12:04:26', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'a8fa7898-0e16-4b03-8a54-4409e2224d4d'	System	12 Aug 2020 16:05:22
User entered 'None (0)'	System	12 Aug 2020 16:05:22

US3522082

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:00:15

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-12T12:04:39', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'a8fa7898-0e16-4b03-8a54-4409e2224d4d'	System	12 Aug 2020 16:05:22
User entered 'Some interference with activity (2)'	System	12 Aug 2020 16:05:22

US3522082

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:00:15

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-12T12:04:43', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'a8fa7898-0e16-4b03-8a54-4409e2224d4d'	System	12 Aug 2020 16:05:22
User entered 'None (0)'	System	12 Aug 2020 16:05:22

US3522082

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:00:15

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-12T12:04:47', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'a8fa7898-0e16-4b03-8a54-4409e2224d4d'	System	12 Aug 2020 16:05:22
User entered 'None (0)'	System	12 Aug 2020 16:05:22

US3522082

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:00:15

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 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-12T12:04:59', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'a8fa7898-0e16-4b03-8a54-4409e2224d4d'	System	12 Aug 2020 16:05:22
User entered 'No (N)'	System	12 Aug 2020 16:05:22

US3522082

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:00:15

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-12T12:05:18', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'a8fa7898-0e16-4b03-8a54-4409e2224d4d'	System	12 Aug 2020 16:05:22
User entered '12 Aug 2020 12:05'	System	12 Aug 2020 16:05:22

US3522082

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:00:15

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 19:01:01

US3522082
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 08:00:15
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 19:01:01

US3522082

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:00:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
Data entry locked.	System	11 Aug 2020 19:01:01
User entered 'Day 3'	System	11 Aug 2020 19:01:01

US3522082
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 08:00:15
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-13T12:16:24', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'f1a2429f-0642-43f2-b194-997f946b9f88'	System	13 Aug 2020 16:17:01
User entered 'None (0)'	System	13 Aug 2020 16:17:01

US3522082
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 08:00:15
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-13T12:16:27', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'f1a2429f-0642-43f2-b194-997f946b9f88'	System	13 Aug 2020 16:17:01
User entered 'None (0)'	System	13 Aug 2020 16:17:01

US3522082
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 08:00:15
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-13T12:16:32', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'f1a2429f-0642-43f2-b194-997f946b9f88'	System	13 Aug 2020 16:17:01
User entered 'None (0)'	System	13 Aug 2020 16:17:01

FDA-CBER-2022-1614-0812047

US3522082

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:00:15

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-13T12:16:36', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'f1a2429f-0642-43f2-b194-997f946b9f88'	System	13 Aug 2020 16:17:01
User entered 'None (0)'	System	13 Aug 2020 16:17:01

US3522082
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 08:00:15
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-13T12:16:41', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'f1a2429f-0642-43f2-b194-997f946b9f88'	System	13 Aug 2020 16:17:01
User entered 'None (0)'	System	13 Aug 2020 16:17:01

US3522082
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 08:00:15
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-13T12:16:44', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'f1a2429f-0642-43f2-b194-997f946b9f88'	System	13 Aug 2020 16:17:01
User entered 'None (0)'	System	13 Aug 2020 16:17:01

US3522082

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:00:15

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 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-13T12:16:50', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'f1a2429f-0642-43f2-b194-997f946b9f88'	System	13 Aug 2020 16:17:01
User entered 'No (N)'	System	13 Aug 2020 16:17:01

US3522082

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:00:15

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-13T12:16:55', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'f1a2429f-0642-43f2-b194-997f946b9f88'	System	13 Aug 2020 16:17:01
User entered '13 Aug 2020 12:16'	System	13 Aug 2020 16:17:01

US3522082

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:00:15

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 19:01:01

US3522082

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:00:15

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 19:01:01

US3522082
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
Data entry locked.	System	11 Aug 2020 19:01:01
User entered 'Day 4'	System	11 Aug 2020 19:01:01

US3522082
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 08:00:15
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-14T17:28:37', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '29e7a900-6789-46c5-8fdc-26efd8d3b637'	System	14 Aug 2020 21:29:11
User entered 'None (0)'	System	14 Aug 2020 21:29:11

US3522082
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 08:00:15
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-14T17:28:40', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '29e7a900-6789-46c5-8fdc-26efd8d3b637'	System	14 Aug 2020 21:29:11
User entered 'None (0)'	System	14 Aug 2020 21:29:11

US3522082

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:00:15

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-14T17:28:43', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '29e7a900-6789-46c5-8fdc-26efd8d3b637'	System	14 Aug 2020 21:29:11
User entered 'None (0)'	System	14 Aug 2020 21:29:11

US3522082

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:00:15

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-14T17:28:46', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '29e7a900-6789-46c5-8fdc-26efd8d3b637'	System	14 Aug 2020 21:29:11
User entered 'None (0)'	System	14 Aug 2020 21:29:11

US3522082

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:00:15

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-14T17:28:50', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '29e7a900-6789-46c5-8fdc-26efd8d3b637'	System	14 Aug 2020 21:29:11
User entered 'None (0)'	System	14 Aug 2020 21:29:11

US3522082

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:00:15

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-14T17:28:53', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '29e7a900-6789-46c5-8fdc-26efd8d3b637'	System	14 Aug 2020 21:29:11
User entered 'None (0)'	System	14 Aug 2020 21:29:11

US3522082

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:00:15

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 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-14T17:29:03', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '29e7a900-6789-46c5-8fdc-26efd8d3b637'	System	14 Aug 2020 21:29:11
User entered 'No (N)'	System	14 Aug 2020 21:29:11

US3522082

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:00:15

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-14T17:29:07', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '29e7a900-6789-46c5-8fdc-26efd8d3b637'	System	14 Aug 2020 21:29:11
User entered '14 Aug 2020 17:29'	System	14 Aug 2020 21:29:11

US3522082

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:00:15

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 19:01:01

US3522082
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 08:00:15
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 19:01:01

US3522082
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
Data entry locked.	System	11 Aug 2020 19:01:01
User entered 'Day 5'	System	11 Aug 2020 19:01:01

US3522082
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 08:00:15
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-15T13:01:53', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'd0f220a5-7bd0-4cd3-bef0-0133bd5c36e0'	System	15 Aug 2020 17:02:32
User entered 'None (0)'	System	15 Aug 2020 17:02:32

US3522082
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 08:00:15
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-15T13:01:56', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'd0f220a5-7bd0-4cd3-bef0-0133bd5c36e0'	System	15 Aug 2020 17:02:32
User entered 'None (0)'	System	15 Aug 2020 17:02:32

US3522082

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:00:15

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-15T13:01:59', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'd0f220a5-7bd0-4cd3-bef0-0133bd5c36e0'	System	15 Aug 2020 17:02:32
User entered 'None (0)'	System	15 Aug 2020 17:02:32

US3522082
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 08:00:15
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-15T13:02:01', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'd0f220a5-7bd0-4cd3-bef0-0133bd5c36e0'	System	15 Aug 2020 17:02:32
User entered 'None (0)'	System	15 Aug 2020 17:02:32

US3522082
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 08:00:15
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-15T13:02:05', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'd0f220a5-7bd0-4cd3-bef0-0133bd5c36e0'	System	15 Aug 2020 17:02:32
User entered 'None (0)'	System	15 Aug 2020 17:02:32

US3522082
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 08:00:15
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-15T13:02:07', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'd0f220a5-7bd0-4cd3-bef0-0133bd5c36e0'	System	15 Aug 2020 17:02:32
User entered 'None (0)'	System	15 Aug 2020 17:02:32

US3522082

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:00:15

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 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-15T13:02:21', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'd0f220a5-7bd0-4cd3-bef0-0133bd5c36e0'	System	15 Aug 2020 17:02:32
User entered 'No (N)'	System	15 Aug 2020 17:02:32

US3522082

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:00:15

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-15T13:02:27', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'd0f220a5-7bd0-4cd3-bef0-0133bd5c36e0'	System	15 Aug 2020 17:02:32
User entered '15 Aug 2020 13:02'	System	15 Aug 2020 17:02:32

US3522082

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:00:15

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 19:01:01

US3522082

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:00:15

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 19:01:01

US3522082
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
Data entry locked.	System	11 Aug 2020 19:01:01
User entered 'Day 6'	System	11 Aug 2020 19:01:01

US3522082
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 08:00:15
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-16T19:32:28', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'dc67f05c-910e-4e35-8ae8-65ef880eee22'	System	16 Aug 2020 23:32:59
User entered 'None (0)'	System	16 Aug 2020 23:32:59

US3522082
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 08:00:15
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-16T19:32:31', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'dc67f05c-910e-4e35-8ae8-65ef880eee22'	System	16 Aug 2020 23:32:59
User entered 'None (0)'	System	16 Aug 2020 23:32:59

US3522082

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:00:15

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-16T19:32:36', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'dc67f05c-910e-4e35-8ae8-65ef880eee22'	System	16 Aug 2020 23:32:59
User entered 'None (0)'	System	16 Aug 2020 23:32:59

US3522082

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:00:15

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-16T19:32:41', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'dc67f05c-910e-4e35-8ae8-65ef880eee22'	System	16 Aug 2020 23:32:59
User entered 'None (0)'	System	16 Aug 2020 23:32:59

US3522082
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 08:00:15
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-16T19:32:44', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'dc67f05c-910e-4e35-8ae8-65ef880eee22'	System	16 Aug 2020 23:32:59
User entered 'None (0)'	System	16 Aug 2020 23:32:59

US3522082
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 08:00:15
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-16T19:32:46', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'dc67f05c-910e-4e35-8ae8-65ef880eee22'	System	16 Aug 2020 23:32:59
User entered 'None (0)'	System	16 Aug 2020 23:32:59

US3522082

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:00:15

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 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-16T19:32:52', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'dc67f05c-910e-4e35-8ae8-65ef880eee22'	System	16 Aug 2020 23:32:59
User entered 'No (N)'	System	16 Aug 2020 23:32:59

US3522082

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:00:15

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-16T19:32:55', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'dc67f05c-910e-4e35-8ae8-65ef880eee22'	System	16 Aug 2020 23:32:59
User entered '16 Aug 2020 19:32'	System	16 Aug 2020 23:32:59

US3522082
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 08:00:15

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 19:01:01

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 19:01:01

US3522082
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
Data entry locked.	System	11 Aug 2020 19:01:01
User entered 'Day 7'	System	11 Aug 2020 19:01:01

US3522082
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 08:00:15
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-17T17:58:49', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '6c3900a0-b45a-4b33-974a-f57a2f9de900'	System	17 Aug 2020 21:59:29
User entered 'None (0)'	System	17 Aug 2020 21:59:29

US3522082
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 08:00:15
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-17T17:58:56', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '6c3900a0-b45a-4b33-974a-f57a2f9de900'	System	17 Aug 2020 21:59:29
User entered 'None (0)'	System	17 Aug 2020 21:59:29

US3522082

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:00:15

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-17T17:59:01', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '6c3900a0-b45a-4b33-974a-f57a2f9de900'	System	17 Aug 2020 21:59:29
User entered 'None (0)'	System	17 Aug 2020 21:59:29

US3522082

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:00:15

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-17T17:59:05', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '6c3900a0-b45a-4b33-974a-f57a2f9de900'	System	17 Aug 2020 21:59:29
User entered 'None (0)'	System	17 Aug 2020 21:59:29

US3522082

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:00:15

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-17T17:59:09', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '6c3900a0-b45a-4b33-974a-f57a2f9de900'	System	17 Aug 2020 21:59:29
User entered 'None (0)'	System	17 Aug 2020 21:59:29

US3522082
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 08:00:15
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-17T17:59:11', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '6c3900a0-b45a-4b33-974a-f57a2f9de900'	System	17 Aug 2020 21:59:29
User entered 'None (0)'	System	17 Aug 2020 21:59:29

US3522082

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:00:15

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 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-17T17:59:18', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '6c3900a0-b45a-4b33-974a-f57a2f9de900'	System	17 Aug 2020 21:59:29
User entered 'No (N)'	System	17 Aug 2020 21:59:29

FDA-CBER-2022-1614-0812095

US3522082

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:00:15

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-08-17T17:59:26', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '6c3900a0-b45a-4b33-974a-f57a2f9de900'	System	17 Aug 2020 21:59:29
User entered '17 Aug 2020 17:59'	System	17 Aug 2020 21:59:29

US3522082
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 08:00:15
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 19:01:01

US3522082
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 08:00:15
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 19:01:01

US3522082

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:00:15

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:34:38
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:41:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Aug 2020 17:23:21

US3522082

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:00:15

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:34:38
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:41:47
User entered '18 Aug 2020'	(b) (4), (b) (6)	18 Aug 2020 17:23:21

US3522082

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:00:15

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:34:38
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:41:47
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	18 Aug 2020 17:23:21

US3522082

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:00:15

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:34:38
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:41:47
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 17:23:21

US3522082

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:00:15

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:34:29
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:41:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Aug 2020 17:23:41

US3522082

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:00:15

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:34:29
User entered '1'	System	18 Aug 2020 17:23:41

US3522082

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:00:15

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:34:29
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:42:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 21:25:57

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:34:29
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:42:04
User entered '26 Aug 2020' reason for change: Data Entry Error	Yaman Ahmed (b) (4) (b) (4)	26 Aug 2020 19:04:07
User entered '25 Aug 2020'	(b) (4), (b) (6)	25 Aug 2020 21:25:57

US3522082

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:00:15

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:34:29
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:42:04
User entered 'Contact Made (CONTACT MADE)' reason for change: New Information	Yaman Ahmed (b) (4)	26 Aug 2020 19:04:07
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4), (b) (6)	25 Aug 2020 21:25:57

US3522082
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 10 Jun 2021 08:00:15
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:34:29
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:42:04
User entered 'Missed call on 26 Aug 2020 and called center back today. No ongoing or new AE reported, no new illness or hospital visits; no changes in health status, medications, Covid-19 exposure' reason for change: Data Entry Error	Yaman Ahmed (b) (4) (b) (4)	26 Aug 2020 19:04:07
User entered 'Left voicemail'	(b) (4), (b) (6)	25 Aug 2020 21:25:57

US3522082

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:00:15

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:34:29
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:42:07
User entered 'Yes (Y)'	Yaman Ahmed (b) (4) (b) (4)	26 Aug 2020 19:04:16

US3522082

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:00:15

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 03:34:29
User entered '1'	System	26 Aug 2020 19:04:16

US3522082

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:00:15

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:07:06
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:51:01
User entered 'Yes (Y)'	Yaman Ahmed (b) (4) (b) (4)	01 Sep 2020 20:29:33

US3522082
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 10 Jun 2021 08:00:15

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:07:06
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:51:01
User entered '1 Sep 2020'	Yaman Ahmed (b) (4) (b) (4)	01 Sep 2020 20:29:33

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:07:06
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 13:51:01
User entered 'Contact Not Made (CONTACT NOT MADE)'	Yaman Ahmed (b) (4) (b) (4)	01 Sep 2020 20:29:33

US3522082
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 10 Jun 2021 08:00:15
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:07:06
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:51:01
User entered 'left a voicemail'	Yaman Ahmed (b) (4) (b) (4)	01 Sep 2020 20:29:33

US3522082

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:00:15

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:07:06
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:53:11
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 17:41:22

US3522082
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 10 Jun 2021 08:00:15
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:07:06
User entered '1'	System	08 Sep 2020 17:41:22

US3522082

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:00:15

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:07:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 17:59:36

US3522082

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:00:15

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:07:31
User entered '8 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 17:59:36

US3522082

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:00:15

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 19:20:48
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:07:31
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	08 Sep 2020 17:59:36

US3522082

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:00:15

Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
User entered 'VISIT2'	System	08 Sep 2020 17:59:36

US3522082

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:00:15

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	08 Sep 2020 18:01:29

US3522082

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:00:15

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:07:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 18:01:29

US3522082

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:00:15

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:07:56
User entered '8 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 18:01:29

US3522082

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:00:15

Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:07:56
User entered '13:35'	(b) (4), (b) (6)	08 Sep 2020 18:01:29

Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 08:00:15

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
User entered '8 Sep 2020 13:35'	System	08 Sep 2020 18:01:29

Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 08:00:15
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:07:56
User entered '97.2' F	(b) (4), (b) (6)	08 Sep 2020 18:01:29

US3522082

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:00:15

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:07:56
User entered 'Other (Other)'	(b) (4), (b) (6)	08 Sep 2020 18:01:29

US3522082

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:00:15

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:07:56
User entered 'temporal'	(b) (4), (b) (6)	08 Sep 2020 18:01:29

US3522082

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:00:15

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:07:56
User entered '84'	(b) (4), (b) (6)	08 Sep 2020 18:01:29

US3522082
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 08:00:15
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
User entered 'bpm'	System	08 Sep 2020 18:01:29

Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 08:00:15
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:07:56
User entered '20'	(b) (4), (b) (6)	08 Sep 2020 18:01:29

US3522082

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:00:15

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
User entered 'breaths/min'	System	08 Sep 2020 18:01:29

US3522082

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:00:15

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:07:56
User entered '129'	(b) (4), (b) (6)	08 Sep 2020 18:01:29

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
User entered 'mmHg'	System	08 Sep 2020 18:01:29

US3522082

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:00:15

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:07:56
User entered '84'	(b) (4), (b) (6)	08 Sep 2020 18:01:29

US3522082

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:00:15

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
User entered 'mmHg'	System	08 Sep 2020 18:01:29

US3522082
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 08:00:15
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	08 Sep 2020 18:01:29

US3522082

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:00:15

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:14:35
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Sep 2020 19:53:49
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 18:01:29

US3522082

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:00:15

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:14:35
User entered '8 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Sep 2020 19:53:49
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 18:01:29

US3522082

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:00:15

Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:14:35
User entered '15:50' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Sep 2020 19:53:49
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 18:01:29

US3522082

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:00:15

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
User entered '8 Sep 2020 15:50'	System	08 Sep 2020 19:53:49
User entered empty.	System	08 Sep 2020 18:01:29

US3522082

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:00:15

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:14:35
User entered '97.3' F reason for change: Data Entry Error	(b) (4), (b) (6)	08 Sep 2020 19:53:49
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 18:01:29

US3522082

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:00:15

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:14:35
User entered 'Other (Other)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Sep 2020 19:53:49
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 18:01:29

US3522082

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:00:15

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:14:35
User entered 'TEMPORAL' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Sep 2020 19:53:49
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 18:01:29

US3522082

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:00:15

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:14:35
User entered '71' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Sep 2020 19:53:49
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 18:01:29

US3522082
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 08:00:15
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
User entered 'bpm'	System	08 Sep 2020 19:53:49
User entered empty.	System	08 Sep 2020 18:01:29

US3522082

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:00:15

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:14:35
User entered '14' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Sep 2020 19:53:49
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 18:01:29

US3522082

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:00:15

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
User entered 'breaths/min'	System	08 Sep 2020 19:53:49
User entered empty.	System	08 Sep 2020 18:01:29

US3522082

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:00:15

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:14:35
User entered '113' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Sep 2020 19:53:49
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 18:01:29

US3522082

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:00:15

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
User entered 'mmHg'	System	08 Sep 2020 19:53:49
User entered empty.	System	08 Sep 2020 18:01:29

US3522082

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:00:15

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:14:35
User entered '76' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Sep 2020 19:53:49
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 18:01:29

Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 08:00:15

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
User entered 'mmHg'	System	08 Sep 2020 19:53:49
User entered empty.	System	08 Sep 2020 18:01:29

US3522082

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:00:15

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:08:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 18:01:36

US3522082

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:00:15

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:08:59
User entered '8 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 18:01:36

US3522082

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:00:15

Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:14:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 19:20:07

US3522082

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:00:15

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:14:12
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 19:20:07

US3522082

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:00:15

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 19:20:48
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:14:12
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 19:20:07

US3522082
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 08:00:15
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
User entered 'MRNA-1273 OR PLACEBO'	System	08 Sep 2020 19:20:07

US3522082

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:00:15

What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:14:12
User entered '8 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 19:20:07

US3522082

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:00:15

What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:14:12
User entered '15:20'	(b) (4), (b) (6)	08 Sep 2020 19:20:07

US3522082
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 08:00:15
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
User entered '8 Sep 2020 15:20'	System	08 Sep 2020 19:20:07

US3522082

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:00:15

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:14:12
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	08 Sep 2020 19:20:07

US3522082

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:00:15

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:14:12
User entered 'ONCE'	System	08 Sep 2020 19:20:07

US3522082

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:00:15

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
User entered 'INTRAMUSCULAR'	System	08 Sep 2020 19:20:07

US3522082

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:00:15

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:53:38
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 17:06:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 18:02:04

US3522082

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:00:15

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:53:38
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
User entered '8 Sep 2020'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:02:04

US3522082

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:00:15

Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:53:38
User closed query 'Per source in EPIC, there is no time of blood draw. Please update source.' (Site from CRA).	(b) (4), (b) (6)	22 Feb 2021 07:26:19
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
Query 'Per source in EPIC, there is no time of blood draw. Please update source.' answered with 'updated, thanks. ' (Site from CRA).	Alayna Wilder (b) (4) (b) (4)	13 Oct 2020 21:13:09
User opened query 'Per source in EPIC, there is no time of blood draw. Please update source.' (Site from CRA).	(b) (4), (b) (6)	08 Oct 2020 15:09:55
User entered '13:47'	(b) (4), (b) (6)	08 Sep 2020 18:02:04

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
User entered '8 Sep 2020 13:47'	System	08 Sep 2020 18:02:04

Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab
Generated On: 10 Jun 2021 08:00:15
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:53:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
User entered '8 Sep 2020'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:02:18

US3522082

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:00:15

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	08 Sep 2020 18:02:18

US3522082

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:00:15

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:53:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 18:02:18

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:00:15

Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:53:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
User entered '13:52'	(b) (4), (b) (6)	08 Sep 2020 18:02:18

US3522082

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:00:15

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
User entered '8 Sep 2020 13:52'	System	08 Sep 2020 18:02:18

US3522082

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:00:15

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	08 Sep 2020 18:02:18

US3522082

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:00:15

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:53:44
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 17:06:52
User entered 'No (N)'	(b) (4), (b) (6)	08 Sep 2020 18:02:18

US3522082

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:00:15

Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:53:44
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 18:02:18

US3522082

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:00:15

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
User entered empty.	System	08 Sep 2020 18:02:18

US3522082
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 10 Jun 2021 08:00:15

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:14:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 18:01:41

US3522082

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:00:15

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
User entered '1'	System	08 Sep 2020 18:01:41

US3522082
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
Data entry locked.	System	08 Sep 2020 19:20:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 19:20:07

US3522082
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 08:00:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-08T15:50:23', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'bb0a4871-055b-4bf1-bd2f-15d139151787'	System	08 Sep 2020 19:50:51
User entered 'Yes (Y)'	System	08 Sep 2020 19:50:51

US3522082

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:00:15

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-08T15:50:34', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'bb0a4871-055b-4bf1-bd2f-15d139151787'	System	08 Sep 2020 19:50:51
User entered '97.3'	System	08 Sep 2020 19:50:51

US3522082

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:00:15

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-08T15:50:39', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'bb0a4871-055b-4bf1-bd2f-15d139151787'	System	08 Sep 2020 19:50:51
User entered 'No (N)'	System	08 Sep 2020 19:50:51

US3522082

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:00:15

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-08T15:50:48', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'bb0a4871-055b-4bf1-bd2f-15d139151787'	System	08 Sep 2020 19:50:51
User entered '08 Sep 2020 15:50'	System	08 Sep 2020 19:50:51

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
User entered '08 Sep 2020 15:40'	System	08 Sep 2020 19:20:07

FDA-CBER-2022-1614-0812185

Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 08:00:15
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
User entered '08 Sep 2020 18:10'	System	08 Sep 2020 19:20:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
Data entry locked.	System	08 Sep 2020 19:20:07
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 19:20:07

US3522082

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:00:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-08T22:16:38', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'a8baf405-909a-4b1c-87c8-ed97b0eab89f'	System	09 Sep 2020 02:17:08
User entered 'Yes (Y)'	System	09 Sep 2020 02:17:08

US3522082

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:00:15

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-08T22:16:46', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'a8baf405-909a-4b1c-87c8-ed97b0eab89f'	System	09 Sep 2020 02:17:08
User entered '96.8'	System	09 Sep 2020 02:17:08

US3522082

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:00:15

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-08T22:16:54', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'a8baf405-909a-4b1c-87c8-ed97b0eab89f'	System	09 Sep 2020 02:17:08
User entered 'No (N)'	System	09 Sep 2020 02:17:08

US3522082

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:00:15

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-08T22:17:05', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'a8baf405-909a-4b1c-87c8-ed97b0eab89f'	System	09 Sep 2020 02:17:08
User entered '08 Sep 2020 22:17'	System	09 Sep 2020 02:17:08

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
User entered '08 Sep 2020 19:05'	System	08 Sep 2020 19:20:07

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 19:20:07

FDA-CBER-2022-1614-0812193

US3522082

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:00:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
Data entry locked.	System	08 Sep 2020 19:20:07
User entered 'Day 2'	System	08 Sep 2020 19:20:07

US3522082

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:00:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-09T20:44:29', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '337b387d-2b69-4268-adfa-6cefe87ab66d'	System	10 Sep 2020 00:44:50
User entered 'Yes (Y)'	System	10 Sep 2020 00:44:50

US3522082

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:00:15

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-09T20:44:38', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '337b387d-2b69-4268-adfa-6cefe87ab66d'	System	10 Sep 2020 00:44:50
User entered '96.4'	System	10 Sep 2020 00:44:50

US3522082

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:00:15

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-09T20:44:43', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '337b387d-2b69-4268-adfa-6cefe87ab66d'	System	10 Sep 2020 00:44:50
User entered 'No (N)'	System	10 Sep 2020 00:44:50

US3522082

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:00:15

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-09T20:44:47', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '337b387d-2b69-4268-adfa-6cefe87ab66d'	System	10 Sep 2020 00:44:50
User entered '09 Sep 2020 20:44'	System	10 Sep 2020 00:44:50

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 19:20:07

FDA-CBER-2022-1614-0812199

US3522082

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:00:15

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 19:20:07

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
Data entry locked.	System	08 Sep 2020 19:20:07
User entered 'Day 3'	System	08 Sep 2020 19:20:07

US3522082
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 08:00:15
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-10T15:48:22', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '1fb4497b-b7c4-43ee-b86f-704aed5c5911'	System	10 Sep 2020 19:48:46
User entered 'Yes (Y)'	System	10 Sep 2020 19:48:46

US3522082
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 08:00:15

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-10T15:48:34', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '1fb4497b-b7c4-43ee-b86f-704aed5c5911'	System	10 Sep 2020 19:48:46
User entered '96.7'	System	10 Sep 2020 19:48:46

US3522082

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:00:15

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-10T15:48:38', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '1fb4497b-b7c4-43ee-b86f-704aed5c5911'	System	10 Sep 2020 19:48:46
User entered 'No (N)'	System	10 Sep 2020 19:48:46

US3522082

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:00:15

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-10T15:48:42', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '1fb4497b-b7c4-43ee-b86f-704aed5c5911'	System	10 Sep 2020 19:48:46
User entered '10 Sep 2020 15:48'	System	10 Sep 2020 19:48:46

US3522082
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 08:00:15

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 19:20:07

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 19:20:07

US3522082
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
Data entry locked.	System	08 Sep 2020 19:20:07
User entered 'Day 4'	System	08 Sep 2020 19:20:07

US3522082

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:00:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-11T19:58:36', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'ec926b93-6236-4f1e-91ab-6ccc8afaf9ec'	System	11 Sep 2020 23:59:00
User entered 'Yes (Y)'	System	11 Sep 2020 23:59:00

US3522082

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:00:15

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-11T19:58:47', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'ec926b93-6236-4f1e-91ab-6ccc8afaf9ec'	System	11 Sep 2020 23:59:00
User entered '96.5'	System	11 Sep 2020 23:59:00

US3522082

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:00:15

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-11T19:58:51', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'ec926b93-6236-4f1e-91ab-6ccc8afaf9ec'	System	11 Sep 2020 23:59:00
User entered 'No (N)'	System	11 Sep 2020 23:59:00

US3522082

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:00:15

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-11T19:58:55', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'ec926b93-6236-4f1e-91ab-6ccc8afaf9ec'	System	11 Sep 2020 23:59:00
User entered '11 Sep 2020 19:58'	System	11 Sep 2020 23:59:00

US3522082

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:00:15

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 19:20:07

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 19:20:07

US3522082
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
Data entry locked.	System	08 Sep 2020 19:20:07
User entered 'Day 5'	System	08 Sep 2020 19:20:07

US3522082

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:00:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-12T13:18:25', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '3ac10810-b67f-4c01-af74-96161927c948'	System	12 Sep 2020 17:18:56
User entered 'Yes (Y)'	System	12 Sep 2020 17:18:56

US3522082

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:00:15

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-12T13:18:40', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '3ac10810-b67f-4c01-af74-96161927c948'	System	12 Sep 2020 17:18:56
User entered '96.7'	System	12 Sep 2020 17:18:56

US3522082

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:00:15

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-12T13:18:47', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '3ac10810-b67f-4c01-af74-96161927c948'	System	12 Sep 2020 17:18:56
User entered 'No (N)'	System	12 Sep 2020 17:18:56

US3522082

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:00:15

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-12T13:18:52', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '3ac10810-b67f-4c01-af74-96161927c948'	System	12 Sep 2020 17:18:56
User entered '12 Sep 2020 13:18'	System	12 Sep 2020 17:18:56

US3522082

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:00:15

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 19:20:07

US3522082

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:00:15

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 19:20:07

US3522082
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
Data entry locked.	System	08 Sep 2020 19:20:07
User entered 'Day 6'	System	08 Sep 2020 19:20:07

US3522082

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:00:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-13T16:39:04', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'c220a1a2-363f-4a5b-9591-72dba25135dc'	System	13 Sep 2020 20:39:27
User entered 'Yes (Y)'	System	13 Sep 2020 20:39:27

US3522082

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:00:15

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-13T16:39:13', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'c220a1a2-363f-4a5b-9591-72dba25135dc'	System	13 Sep 2020 20:39:27
User entered '97.4'	System	13 Sep 2020 20:39:27

US3522082

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:00:15

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-13T16:39:18', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'c220a1a2-363f-4a5b-9591-72dba25135dc'	System	13 Sep 2020 20:39:27
User entered 'No (N)'	System	13 Sep 2020 20:39:27

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-13T16:39:25', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'c220a1a2-363f-4a5b-9591-72dba25135dc'	System	13 Sep 2020 20:39:27
User entered '13 Sep 2020 16:39'	System	13 Sep 2020 20:39:27

US3522082

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:00:15

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 19:20:07

US3522082
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 08:00:15
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 19:20:07

US3522082
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
Data entry locked.	System	08 Sep 2020 19:20:07
User entered 'Day 7'	System	08 Sep 2020 19:20:07

US3522082

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:00:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-14T18:46:54', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '13aed119-5b4f-49df-9625-13b4e93970db'	System	14 Sep 2020 22:47:22
User entered 'Yes (Y)'	System	14 Sep 2020 22:47:22

US3522082

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:00:15

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-14T18:47:07', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '13aed119-5b4f-49df-9625-13b4e93970db'	System	14 Sep 2020 22:47:22
User entered '97.5'	System	14 Sep 2020 22:47:22

US3522082

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:00:15

Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-14T18:47:15', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '13aed119-5b4f-49df-9625-13b4e93970db'	System	14 Sep 2020 22:47:22
User entered 'No (N)'	System	14 Sep 2020 22:47:22

US3522082

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:00:15

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-14T18:47:18', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '13aed119-5b4f-49df-9625-13b4e93970db'	System	14 Sep 2020 22:47:22
User entered '14 Sep 2020 18:47'	System	14 Sep 2020 22:47:22

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 19:20:07

US3522082
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 08:00:15
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 19:20:07

US3522082
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
Data entry locked.	System	08 Sep 2020 19:20:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 19:20:07

US3522082

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:00:15

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 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-08T15:40:44', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '02bcc956-5e3b-444e-81a5-d17030acc93d'	System	08 Sep 2020 19:41:23
User entered 'None (1)'	System	08 Sep 2020 19:41:23

US3522082

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:00:15

Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-08T15:40:52', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '02bcc956-5e3b-444e-81a5-d17030acc93d'	System	08 Sep 2020 19:41:23
User entered 'No (N)'	System	08 Sep 2020 19:41:23

US3522082

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:00:15

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-08T15:40:57', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '02bcc956-5e3b-444e-81a5-d17030acc93d'	System	08 Sep 2020 19:41:23
User entered 'No (N)'	System	08 Sep 2020 19:41:23

US3522082

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:00:15

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 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-08T15:41:02', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '02bcc956-5e3b-444e-81a5-d17030acc93d'	System	08 Sep 2020 19:41:23
User entered 'None (1)'	System	08 Sep 2020 19:41:23

US3522082
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 08:00:15
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-08T15:41:15', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '02bcc956-5e3b-444e-81a5-d17030acc93d'	System	08 Sep 2020 19:41:23
User entered '08 Sep 2020 15:41'	System	08 Sep 2020 19:41:23

US3522082

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:00:15

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
User entered '08 Sep 2020 15:40'	System	08 Sep 2020 19:20:07

US3522082
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 08:00:15
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
User entered '08 Sep 2020 18:10'	System	08 Sep 2020 19:20:07

US3522082
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
Data entry locked.	System	08 Sep 2020 19:20:07
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 19:20:07

US3522082

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:00:15

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 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-08T22:17:32', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '39826744-b200-4545-965d-033379bdd927'	System	09 Sep 2020 02:20:30
User entered 'Does not interfere with activity (2)'	System	09 Sep 2020 02:20:30

US3522082

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:00:15

Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-08T22:17:46', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '39826744-b200-4545-965d-033379bdd927'	System	09 Sep 2020 02:20:30
User entered 'No (N)'	System	09 Sep 2020 02:20:30

FDA-CBER-2022-1614-0812246

US3522082

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:00:15

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-08T22:18:24', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '39826744-b200-4545-965d-033379bdd927'	System	09 Sep 2020 02:20:30
User entered 'Yes (Y)'	System	09 Sep 2020 02:20:30

US3522082

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:00:15

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 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-08T22:19:44', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '39826744-b200-4545-965d-033379bdd927'	System	09 Sep 2020 02:20:30
User entered '7'	System	09 Sep 2020 02:20:30

US3522082

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:00:15

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 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-08T22:19:59', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '39826744-b200-4545-965d-033379bdd927'	System	09 Sep 2020 02:20:30
User entered 'None (1)'	System	09 Sep 2020 02:20:30

US3522082
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 08:00:15
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-08T22:20:25', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '39826744-b200-4545-965d-033379bdd927'	System	09 Sep 2020 02:20:30
User entered '08 Sep 2020 22:20'	System	09 Sep 2020 02:20:30

US3522082

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:00:15

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
User entered '08 Sep 2020 19:05'	System	08 Sep 2020 19:20:07

US3522082
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 08:00:15
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 19:20:07

US3522082
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
Data entry locked.	System	08 Sep 2020 19:20:07
User entered 'Day 2'	System	08 Sep 2020 19:20:07

US3522082

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:00:15

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 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-09T20:45:16', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '5fc54a7c-0a58-430e-854a-5ee535a5afa7'	System	10 Sep 2020 00:45:40
User entered 'Does not interfere with activity (2)'	System	10 Sep 2020 00:45:40

US3522082
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 08:00:15

Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-09T20:45:20', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '5fc54a7c-0a58-430e-854a-5ee535a5afa7'	System	10 Sep 2020 00:45:40
User entered 'No (N)'	System	10 Sep 2020 00:45:40

US3522082

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:00:15

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-09T20:45:24', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '5fc54a7c-0a58-430e-854a-5ee535a5afa7'	System	10 Sep 2020 00:45:40
User entered 'No (N)'	System	10 Sep 2020 00:45:40

US3522082

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:00:15

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 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-09T20:45:30', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '5fc54a7c-0a58-430e-854a-5ee535a5afa7'	System	10 Sep 2020 00:45:40
User entered 'None (1)'	System	10 Sep 2020 00:45:40

US3522082

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:00:15

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-09T20:45:36', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '5fc54a7c-0a58-430e-854a-5ee535a5afa7'	System	10 Sep 2020 00:45:40
User entered '09 Sep 2020 20:45'	System	10 Sep 2020 00:45:40

US3522082
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 08:00:15
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 19:20:07

US3522082

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:00:15

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 19:20:07

US3522082
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
Data entry locked.	System	08 Sep 2020 19:20:07
User entered 'Day 3'	System	08 Sep 2020 19:20:07

US3522082

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:00:15

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 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-10T15:48:56', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '1e677120-0f57-4333-a43d-a595c190e74c'	System	10 Sep 2020 19:49:15
User entered 'None (1)'	System	10 Sep 2020 19:49:15

US3522082

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:00:15

Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-10T15:49:00', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '1e677120-0f57-4333-a43d-a595c190e74c'	System	10 Sep 2020 19:49:15
User entered 'No (N)'	System	10 Sep 2020 19:49:15

US3522082

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:00:15

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-10T15:49:03', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '1e677120-0f57-4333-a43d-a595c190e74c'	System	10 Sep 2020 19:49:15
User entered 'No (N)'	System	10 Sep 2020 19:49:15

US3522082

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:00:15

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 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-10T15:49:05', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '1e677120-0f57-4333-a43d-a595c190e74c'	System	10 Sep 2020 19:49:15
User entered 'None (1)'	System	10 Sep 2020 19:49:15

US3522082

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:00:15

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-10T15:49:08', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '1e677120-0f57-4333-a43d-a595c190e74c'	System	10 Sep 2020 19:49:15
User entered '10 Sep 2020 15:49'	System	10 Sep 2020 19:49:15

US3522082

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:00:15

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 19:20:07

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 19:20:07

US3522082
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
Data entry locked.	System	08 Sep 2020 19:20:07
User entered 'Day 4'	System	08 Sep 2020 19:20:07

US3522082

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:00:15

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 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-11T19:57:26', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '97ee81b6-104e-4e00-ad6e-296801bd3c31'	System	11 Sep 2020 23:57:45
User entered 'None (1)'	System	11 Sep 2020 23:57:45

US3522082

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:00:15

Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-11T19:57:31', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '97ee81b6-104e-4e00-ad6e-296801bd3c31'	System	11 Sep 2020 23:57:45
User entered 'No (N)'	System	11 Sep 2020 23:57:45

US3522082

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:00:15

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-11T19:57:35', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '97ee81b6-104e-4e00-ad6e-296801bd3c31'	System	11 Sep 2020 23:57:45
User entered 'No (N)'	System	11 Sep 2020 23:57:45

US3522082

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:00:15

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 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-11T19:57:38', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '97ee81b6-104e-4e00-ad6e-296801bd3c31'	System	11 Sep 2020 23:57:45
User entered 'None (1)'	System	11 Sep 2020 23:57:45

US3522082

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:00:15

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-11T19:57:42', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '97ee81b6-104e-4e00-ad6e-296801bd3c31'	System	11 Sep 2020 23:57:45
User entered '11 Sep 2020 19:57'	System	11 Sep 2020 23:57:45

US3522082

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:00:15

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 19:20:07

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 19:20:07

FDA-CBER-2022-1614-0812276

US3522082
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
Data entry locked.	System	08 Sep 2020 19:20:07
User entered 'Day 5'	System	08 Sep 2020 19:20:07

US3522082

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:00:15

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 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-12T13:18:58', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'a54eeeab-625b-4947-b979-c212740c4044'	System	12 Sep 2020 17:19:23
User entered 'None (1)'	System	12 Sep 2020 17:19:23

US3522082

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:00:15

Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-12T13:19:06', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'a54eeeab-625b-4947-b979-c212740c4044'	System	12 Sep 2020 17:19:23
User entered 'No (N)'	System	12 Sep 2020 17:19:23

US3522082

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:00:15

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-12T13:19:10', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'a54eeeab-625b-4947-b979-c212740c4044'	System	12 Sep 2020 17:19:23
User entered 'No (N)'	System	12 Sep 2020 17:19:23

US3522082

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:00:15

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 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-12T13:19:13', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'a54eeeab-625b-4947-b979-c212740c4044'	System	12 Sep 2020 17:19:23
User entered 'None (1)'	System	12 Sep 2020 17:19:23

US3522082
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 08:00:15
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-12T13:19:19', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'a54eeeab-625b-4947-b979-c212740c4044'	System	12 Sep 2020 17:19:23
User entered '12 Sep 2020 13:19'	System	12 Sep 2020 17:19:23

US3522082
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 08:00:15
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 19:20:07

US3522082
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 08:00:15
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 19:20:07

US3522082
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
Data entry locked.	System	08 Sep 2020 19:20:07
User entered 'Day 6'	System	08 Sep 2020 19:20:07

US3522082

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:00:15

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 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-13T16:39:32', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '15dae2f1-ae77-4d04-b6a4-ca70c7684d76'	System	13 Sep 2020 20:39:52
User entered 'None (1)'	System	13 Sep 2020 20:39:52

US3522082

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:00:15

Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-13T16:39:36', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '15dae2f1-ae77-4d04-b6a4-ca70c7684d76'	System	13 Sep 2020 20:39:52
User entered 'No (N)'	System	13 Sep 2020 20:39:52

FDA-CBER-2022-1614-0812287

US3522082

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:00:15

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-13T16:39:41', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '15dae2f1-ae77-4d04-b6a4-ca70c7684d76'	System	13 Sep 2020 20:39:52
User entered 'No (N)'	System	13 Sep 2020 20:39:52

US3522082

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:00:15

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 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-13T16:39:45', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '15dae2f1-ae77-4d04-b6a4-ca70c7684d76'	System	13 Sep 2020 20:39:52
User entered 'None (1)'	System	13 Sep 2020 20:39:52

US3522082

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:00:15

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-13T16:39:49', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '15dae2f1-ae77-4d04-b6a4-ca70c7684d76'	System	13 Sep 2020 20:39:52
User entered '13 Sep 2020 16:39'	System	13 Sep 2020 20:39:52

US3522082
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 08:00:15
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 19:20:07

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 19:20:07

US3522082
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
Data entry locked.	System	08 Sep 2020 19:20:07
User entered 'Day 7'	System	08 Sep 2020 19:20:07

US3522082

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:00:15

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 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-14T18:47:28', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'a9ff7267-221d-4981-8d6a-60f62f528786'	System	14 Sep 2020 22:48:04
User entered 'None (1)'	System	14 Sep 2020 22:48:04

US3522082

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:00:15

Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-14T18:47:36', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'a9ff7267-221d-4981-8d6a-60f62f528786'	System	14 Sep 2020 22:48:04
User entered 'No (N)'	System	14 Sep 2020 22:48:04

US3522082

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:00:15

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-14T18:47:51', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'a9ff7267-221d-4981-8d6a-60f62f528786'	System	14 Sep 2020 22:48:04
User entered 'No (N)'	System	14 Sep 2020 22:48:04

US3522082

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:00:15

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 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-14T18:47:54', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'a9ff7267-221d-4981-8d6a-60f62f528786'	System	14 Sep 2020 22:48:04
User entered 'None (1)'	System	14 Sep 2020 22:48:04

US3522082

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:00:15

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-14T18:47:58', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'a9ff7267-221d-4981-8d6a-60f62f528786'	System	14 Sep 2020 22:48:04
User entered '14 Sep 2020 18:47'	System	14 Sep 2020 22:48:04

US3522082

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:00:15

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 19:20:07

US3522082
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 08:00:15
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 19:20:07

US3522082
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
Data entry locked.	System	08 Sep 2020 19:20:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 19:20:07

US3522082

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:00:15

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-08T15:41:26', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'a88aa3b0-5f1a-48d2-b901-e0ce4e6290e5'	System	08 Sep 2020 19:42:12
User entered 'None (0)'	System	08 Sep 2020 19:42:12

US3522082
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 08:00:15
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-08T15:41:31', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'a88aa3b0-5f1a-48d2-b901-e0ce4e6290e5'	System	08 Sep 2020 19:42:12
User entered 'None (0)'	System	08 Sep 2020 19:42:12

US3522082

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:00:15

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-08T15:41:35', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'a88aa3b0-5f1a-48d2-b901-e0ce4e6290e5'	System	08 Sep 2020 19:42:12
User entered 'None (0)'	System	08 Sep 2020 19:42:12

US3522082

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:00:15

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-08T15:41:39', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'a88aa3b0-5f1a-48d2-b901-e0ce4e6290e5'	System	08 Sep 2020 19:42:12
User entered 'None (0)'	System	08 Sep 2020 19:42:12

US3522082

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:00:15

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-08T15:41:43', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'a88aa3b0-5f1a-48d2-b901-e0ce4e6290e5'	System	08 Sep 2020 19:42:12
User entered 'None (0)'	System	08 Sep 2020 19:42:12

US3522082
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 08:00:15
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-08T15:41:47', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'a88aa3b0-5f1a-48d2-b901-e0ce4e6290e5'	System	08 Sep 2020 19:42:12
User entered 'None (0)'	System	08 Sep 2020 19:42:12

US3522082

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:00:15

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 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-08T15:41:54', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'a88aa3b0-5f1a-48d2-b901-e0ce4e6290e5'	System	08 Sep 2020 19:42:12
User entered 'No (N)'	System	08 Sep 2020 19:42:12

US3522082

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:00:15

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-08T15:42:09', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'a88aa3b0-5f1a-48d2-b901-e0ce4e6290e5'	System	08 Sep 2020 19:42:12
User entered '08 Sep 2020 15:42'	System	08 Sep 2020 19:42:12

US3522082

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:00:15

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
User entered '08 Sep 2020 15:40'	System	08 Sep 2020 19:20:07

US3522082

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:00:15

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
User entered '08 Sep 2020 18:10'	System	08 Sep 2020 19:20:07

US3522082
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
Data entry locked.	System	08 Sep 2020 19:20:07
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 19:20:07

US3522082
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 08:00:15
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-08T22:20:34', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'c304d43f-bf98-4e3e-b5c2-97d2c2fffbeb'	System	09 Sep 2020 02:21:23
User entered 'None (0)'	System	09 Sep 2020 02:21:23

US3522082
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 08:00:15
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-08T22:20:40', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'c304d43f-bf98-4e3e-b5c2-97d2c2fffbeb'	System	09 Sep 2020 02:21:23
User entered 'None (0)'	System	09 Sep 2020 02:21:23

US3522082
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 08:00:15
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-08T22:20:46', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'c304d43f-bf98-4e3e-b5c2-97d2c2fffbeb'	System	09 Sep 2020 02:21:23
User entered 'None (0)'	System	09 Sep 2020 02:21:23

US3522082

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:00:15

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-08T22:20:51', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'c304d43f-bf98-4e3e-b5c2-97d2c2fffbeb'	System	09 Sep 2020 02:21:23
User entered 'None (0)'	System	09 Sep 2020 02:21:23

US3522082
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 08:00:15
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-08T22:20:55', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'c304d43f-bf98-4e3e-b5c2-97d2c2fffbeb'	System	09 Sep 2020 02:21:23
User entered 'None (0)'	System	09 Sep 2020 02:21:23

US3522082
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 08:00:15
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-08T22:20:59', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'c304d43f-bf98-4e3e-b5c2-97d2c2fffbeb'	System	09 Sep 2020 02:21:23
User entered 'None (0)'	System	09 Sep 2020 02:21:23

US3522082

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:00:15

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 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-08T22:21:13', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'c304d43f-bf98-4e3e-b5c2-97d2c2fffbeb'	System	09 Sep 2020 02:21:23
User entered 'No (N)'	System	09 Sep 2020 02:21:23

US3522082

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:00:15

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-08T22:21:20', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'c304d43f-bf98-4e3e-b5c2-97d2c2fffbeb'	System	09 Sep 2020 02:21:23
User entered '08 Sep 2020 22:21'	System	09 Sep 2020 02:21:23

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
User entered '08 Sep 2020 19:05'	System	08 Sep 2020 19:20:07

US3522082

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:00:15

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 19:20:07

US3522082
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
Data entry locked.	System	08 Sep 2020 19:20:07
User entered 'Day 2'	System	08 Sep 2020 19:20:07

US3522082

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:00:15

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-09T20:45:43', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'daaee89b-dbb8-4da0-8c71-3ec41de921b1'	System	10 Sep 2020 00:46:15
User entered 'None (0)'	System	10 Sep 2020 00:46:15

FDA-CBER-2022-1614-0812324

US3522082
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 08:00:15
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-09T20:45:48', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'daaee89b-dbb8-4da0-8c71-3ec41de921b1'	System	10 Sep 2020 00:46:15
User entered 'None (0)'	System	10 Sep 2020 00:46:15

US3522082

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:00:15

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-09T20:45:53', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'daaee89b-dbb8-4da0-8c71-3ec41de921b1'	System	10 Sep 2020 00:46:15
User entered 'None (0)'	System	10 Sep 2020 00:46:15

FDA-CBER-2022-1614-0812326

US3522082

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:00:15

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-09T20:45:56', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'daaee89b-dbb8-4da0-8c71-3ec41de921b1'	System	10 Sep 2020 00:46:15
User entered 'None (0)'	System	10 Sep 2020 00:46:15

US3522082
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 08:00:15
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-09T20:45:59', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'daaee89b-dbb8-4da0-8c71-3ec41de921b1'	System	10 Sep 2020 00:46:15
User entered 'None (0)'	System	10 Sep 2020 00:46:15

US3522082
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 08:00:15
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-09T20:46:02', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'daaee89b-dbb8-4da0-8c71-3ec41de921b1'	System	10 Sep 2020 00:46:15
User entered 'None (0)'	System	10 Sep 2020 00:46:15

US3522082

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:00:15

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 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-09T20:46:05', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'daaee89b-dbb8-4da0-8c71-3ec41de921b1'	System	10 Sep 2020 00:46:15
User entered 'No (N)'	System	10 Sep 2020 00:46:15

US3522082

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:00:15

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-09T20:46:08', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'daaee89b-dbb8-4da0-8c71-3ec41de921b1'	System	10 Sep 2020 00:46:15
User entered '09 Sep 2020 20:46'	System	10 Sep 2020 00:46:15

US3522082
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 08:00:15
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 19:20:07

US3522082

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:00:15

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 19:20:07

US3522082
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
Data entry locked.	System	08 Sep 2020 19:20:07
User entered 'Day 3'	System	08 Sep 2020 19:20:07

US3522082
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 08:00:15
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-10T15:49:14', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '71272fbb-bde8-4368-98b4-f01aa800050d'	System	10 Sep 2020 19:50:03
User entered 'None (0)'	System	10 Sep 2020 19:50:03

US3522082
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 08:00:15
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-10T15:49:18', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '71272fbb-bde8-4368-98b4-f01aa800050d'	System	10 Sep 2020 19:50:03
User entered 'None (0)'	System	10 Sep 2020 19:50:03

US3522082

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:00:15

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-10T15:49:32', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '71272fbb-bde8-4368-98b4-f01aa800050d'	System	10 Sep 2020 19:50:03
User entered 'None (0)'	System	10 Sep 2020 19:50:03

US3522082

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:00:15

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-10T15:49:40', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '71272fbb-bde8-4368-98b4-f01aa800050d'	System	10 Sep 2020 19:50:03
User entered 'None (0)'	System	10 Sep 2020 19:50:03

US3522082
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 08:00:15
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-10T15:49:45', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '71272fbb-bde8-4368-98b4-f01aa800050d'	System	10 Sep 2020 19:50:03
User entered 'None (0)'	System	10 Sep 2020 19:50:03

US3522082
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 08:00:15
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-10T15:49:47', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '71272fbb-bde8-4368-98b4-f01aa800050d'	System	10 Sep 2020 19:50:03
User entered 'None (0)'	System	10 Sep 2020 19:50:03

US3522082

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:00:15

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 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-10T15:49:51', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '71272fbb-bde8-4368-98b4-f01aa800050d'	System	10 Sep 2020 19:50:03
User entered 'No (N)'	System	10 Sep 2020 19:50:03

US3522082

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:00:15

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-10T15:49:56', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '71272fbb-bde8-4368-98b4-f01aa800050d'	System	10 Sep 2020 19:50:03
User entered '10 Sep 2020 15:49'	System	10 Sep 2020 19:50:03

US3522082

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:00:15

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 19:20:07

US3522082

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:00:15

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 19:20:07

US3522082
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
Data entry locked.	System	08 Sep 2020 19:20:07
User entered 'Day 4'	System	08 Sep 2020 19:20:07

US3522082

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:00:15

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-11T19:56:49', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '036be265-63f6-4820-812d-92f4fe676e7a'	System	11 Sep 2020 23:57:17
User entered 'None (0)'	System	11 Sep 2020 23:57:17

US3522082
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 08:00:15
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-11T19:56:52', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '036be265-63f6-4820-812d-92f4fe676e7a'	System	11 Sep 2020 23:57:17
User entered 'None (0)'	System	11 Sep 2020 23:57:17

US3522082
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 08:00:15
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-11T19:56:55', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '036be265-63f6-4820-812d-92f4fe676e7a'	System	11 Sep 2020 23:57:17
User entered 'None (0)'	System	11 Sep 2020 23:57:17

US3522082
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 08:00:15
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-11T19:56:58', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '036be265-63f6-4820-812d-92f4fe676e7a'	System	11 Sep 2020 23:57:17
User entered 'None (0)'	System	11 Sep 2020 23:57:17

US3522082
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 08:00:15
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-11T19:57:03', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '036be265-63f6-4820-812d-92f4fe676e7a'	System	11 Sep 2020 23:57:17
User entered 'None (0)'	System	11 Sep 2020 23:57:17

US3522082
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 08:00:15
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-11T19:57:06', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '036be265-63f6-4820-812d-92f4fe676e7a'	System	11 Sep 2020 23:57:17
User entered 'None (0)'	System	11 Sep 2020 23:57:17

US3522082

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:00:15

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 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-11T19:57:10', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '036be265-63f6-4820-812d-92f4fe676e7a'	System	11 Sep 2020 23:57:17
User entered 'No (N)'	System	11 Sep 2020 23:57:17

US3522082

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:00:15

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-11T19:57:14', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '036be265-63f6-4820-812d-92f4fe676e7a'	System	11 Sep 2020 23:57:17
User entered '11 Sep 2020 19:57'	System	11 Sep 2020 23:57:17

US3522082

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:00:15

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 19:20:07

US3522082

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:00:15

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 19:20:07

US3522082
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
Data entry locked.	System	08 Sep 2020 19:20:07
User entered 'Day 5'	System	08 Sep 2020 19:20:07

US3522082

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:00:15

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-12T13:19:25', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '7d503e77-b5ee-4c22-9e21-e4d89cde14f5'	System	12 Sep 2020 17:19:48
User entered 'None (0)'	System	12 Sep 2020 17:19:48

US3522082
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 08:00:15
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-12T13:19:28', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '7d503e77-b5ee-4c22-9e21-e4d89cde14f5'	System	12 Sep 2020 17:19:48
User entered 'None (0)'	System	12 Sep 2020 17:19:48

US3522082

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:00:15

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-12T13:19:30', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '7d503e77-b5ee-4c22-9e21-e4d89cde14f5'	System	12 Sep 2020 17:19:48
User entered 'None (0)'	System	12 Sep 2020 17:19:48

US3522082

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:00:15

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-12T13:19:33', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '7d503e77-b5ee-4c22-9e21-e4d89cde14f5'	System	12 Sep 2020 17:19:48
User entered 'None (0)'	System	12 Sep 2020 17:19:48

US3522082
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 08:00:15
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-12T13:19:36', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '7d503e77-b5ee-4c22-9e21-e4d89cde14f5'	System	12 Sep 2020 17:19:48
User entered 'None (0)'	System	12 Sep 2020 17:19:48

US3522082
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 08:00:15
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-12T13:19:39', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '7d503e77-b5ee-4c22-9e21-e4d89cde14f5'	System	12 Sep 2020 17:19:48
User entered 'None (0)'	System	12 Sep 2020 17:19:48

US3522082

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:00:15

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 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-12T13:19:41', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '7d503e77-b5ee-4c22-9e21-e4d89cde14f5'	System	12 Sep 2020 17:19:48
User entered 'No (N)'	System	12 Sep 2020 17:19:48

FDA-CBER-2022-1614-0812363

US3522082

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:00:15

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-12T13:19:45', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '7d503e77-b5ee-4c22-9e21-e4d89cde14f5'	System	12 Sep 2020 17:19:48
User entered '12 Sep 2020 13:19'	System	12 Sep 2020 17:19:48

US3522082
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 08:00:15
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 19:20:07

US3522082

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:00:15

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 19:20:07

US3522082
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
Data entry locked.	System	08 Sep 2020 19:20:07
User entered 'Day 6'	System	08 Sep 2020 19:20:07

US3522082
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 08:00:15
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-13T16:40:00', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'd1bb3842-12a4-4cf9-9a45-49650893fea6'	System	13 Sep 2020 20:41:00
User entered 'None (0)'	System	13 Sep 2020 20:41:00

US3522082
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 08:00:15
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-13T16:40:03', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'd1bb3842-12a4-4cf9-9a45-49650893fea6'	System	13 Sep 2020 20:41:00
User entered 'None (0)'	System	13 Sep 2020 20:41:00

US3522082

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:00:15

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-13T16:40:31', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'd1bb3842-12a4-4cf9-9a45-49650893fea6'	System	13 Sep 2020 20:41:00
User entered 'None (0)'	System	13 Sep 2020 20:41:00

US3522082

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:00:15

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-13T16:40:35', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'd1bb3842-12a4-4cf9-9a45-49650893fea6'	System	13 Sep 2020 20:41:00
User entered 'None (0)'	System	13 Sep 2020 20:41:00

US3522082
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 08:00:15
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-13T16:40:38', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'd1bb3842-12a4-4cf9-9a45-49650893fea6'	System	13 Sep 2020 20:41:00
User entered 'None (0)'	System	13 Sep 2020 20:41:00

US3522082
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 08:00:15
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-13T16:40:41', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'd1bb3842-12a4-4cf9-9a45-49650893fea6'	System	13 Sep 2020 20:41:00
User entered 'None (0)'	System	13 Sep 2020 20:41:00

US3522082

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:00:15

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 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-13T16:40:44', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'd1bb3842-12a4-4cf9-9a45-49650893fea6'	System	13 Sep 2020 20:41:00
User entered 'No (N)'	System	13 Sep 2020 20:41:00

US3522082

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:00:15

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-13T16:40:55', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'd1bb3842-12a4-4cf9-9a45-49650893fea6'	System	13 Sep 2020 20:41:00
User entered '13 Sep 2020 16:40'	System	13 Sep 2020 20:41:00

US3522082

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:00:15

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 19:20:07

US3522082

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:00:15

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 19:20:07

US3522082
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
Data entry locked.	System	08 Sep 2020 19:20:07
User entered 'Day 7'	System	08 Sep 2020 19:20:07

US3522082
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 08:00:15
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-14T18:48:13', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '688580d4-7df9-41b2-a553-c5a1d4b8dbe2'	System	14 Sep 2020 22:48:37
User entered 'None (0)'	System	14 Sep 2020 22:48:37

US3522082
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 08:00:15
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-14T18:48:16', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '688580d4-7df9-41b2-a553-c5a1d4b8dbe2'	System	14 Sep 2020 22:48:37
User entered 'None (0)'	System	14 Sep 2020 22:48:37

US3522082

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:00:15

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-14T18:48:19', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '688580d4-7df9-41b2-a553-c5a1d4b8dbe2'	System	14 Sep 2020 22:48:37
User entered 'None (0)'	System	14 Sep 2020 22:48:37

US3522082

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:00:15

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-14T18:48:22', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '688580d4-7df9-41b2-a553-c5a1d4b8dbe2'	System	14 Sep 2020 22:48:37
User entered 'None (0)'	System	14 Sep 2020 22:48:37

US3522082
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 08:00:15
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-14T18:48:24', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '688580d4-7df9-41b2-a553-c5a1d4b8dbe2'	System	14 Sep 2020 22:48:37
User entered 'None (0)'	System	14 Sep 2020 22:48:37

US3522082
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 08:00:15
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-14T18:48:27', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '688580d4-7df9-41b2-a553-c5a1d4b8dbe2'	System	14 Sep 2020 22:48:37
User entered 'None (0)'	System	14 Sep 2020 22:48:37

US3522082

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:00:15

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 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-14T18:48:29', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '688580d4-7df9-41b2-a553-c5a1d4b8dbe2'	System	14 Sep 2020 22:48:37
User entered 'No (N)'	System	14 Sep 2020 22:48:37

US3522082

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:00:15

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-09-14T18:48:32', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '688580d4-7df9-41b2-a553-c5a1d4b8dbe2'	System	14 Sep 2020 22:48:37
User entered '14 Sep 2020 18:48'	System	14 Sep 2020 22:48:37

US3522082

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:00:15

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 19:20:07

US3522082

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:00:15

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 19:20:07

US3522082

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:00:15

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:15:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Sep 2020 18:59:54

US3522082

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:00:15

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:15:20
User entered '15 Sep 2020'	(b) (4), (b) (6)	15 Sep 2020 18:59:54

US3522082

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:00:15

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:15:20
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	15 Sep 2020 18:59:54

US3522082

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:00:15

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:15:20
User entered "'No ongoing or new AE reported, no new illness or hospital visits; no changes in health status, medications, Covid-19 exposure or pregnancy risk.'"	(b) (4), (b) (6)	15 Sep 2020 18:59:54

US3522082

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:00:15

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:15:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Sep 2020 18:59:58

US3522082
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 10 Jun 2021 08:00:15
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
User entered '1'	System	15 Sep 2020 18:59:58

US3522082

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:00:15

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:16:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 17:57:40

US3522082

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:00:15

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:16:45
User entered '22 Sep 2020'	(b) (4), (b) (6)	22 Sep 2020 17:57:40

US3522082

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:00:15

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:16:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	22 Sep 2020 17:57:40

US3522082

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:00:15

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:16:45
User entered 'No ongoing or new AE reported, no new illness or hospital visits; no changes in health status, medications, Covid-19 exposure or pregnancy risk.'	(b) (4), (b) (6)	22 Sep 2020 17:57:40

US3522082

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:00:15

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:16:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 17:57:46

US3522082
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 10 Jun 2021 08:00:15
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
User entered '1'	System	22 Sep 2020 17:57:46

US3522082
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 10 Jun 2021 08:00:15

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:21:18
User entered 'Yes (Y)'	Yaman Ahmed (b) (4) (b) (4)	29 Sep 2020 14:56:45

US3522082

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:00:15

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:21:18
User entered '30 Sep 2020' reason for change: Data Entry Error	Kristin Eis (b) (4) (b) (4)	30 Sep 2020 17:25:36
User entered '29 Sep 2020'	Yaman Ahmed (b) (4) (b) (4)	29 Sep 2020 14:56:45

US3522082

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:00:15

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:21:18
User entered 'Contact Made (CONTACT MADE)' reason for change: Data Entry Error	Kristin Eis (b) (4) (b) (4)	30 Sep 2020 17:25:36
User entered 'Contact Not Made (CONTACT NOT MADE)'	Yaman Ahmed (b) (4) (b) (4)	29 Sep 2020 14:56:45

US3522082

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:00:15

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:21:18
User entered 'No ongoing or new AE reported, no new illness or hospital visits; no changes in health status, medications, Covid-19 exposure or pregnancy risk.' reason for change: Data Entry Error	Kristin Eis (b) (4) (b) (4)	30 Sep 2020 17:25:36
User entered 'left a voicemail'	Yaman Ahmed (b) (4) (b) (4)	29 Sep 2020 14:56:45

US3522082

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:00:15

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 17:06:52
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 15:21:22
User entered 'Yes (Y)'	Kristin Eis (b) (4) (b) (4)	30 Sep 2020 17:25:41

US3522082
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 10 Jun 2021 08:00:15
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
User entered '1'	System	30 Sep 2020 17:25:41

US3522082

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:00:15

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 00:26:37
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 12:53:38

US3522082
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 10 Jun 2021 08:00:15

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 00:26:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 17:06:52
User closed query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	05 Oct 2020 07:27:56
Query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' answered with 'Patient request, ok per study doctor' (Site from System).	(b) (4), (b) (6)	02 Oct 2020 12:55:24
User opened query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	System	02 Oct 2020 12:53:38
User entered '2 Oct 2020'	(b) (4), (b) (6)	02 Oct 2020 12:53:38

FDA-CBER-2022-1614-0812408

US3522082
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 10 Jun 2021 08:00:15

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 19:20:48
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 00:26:37
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 12:53:38

US3522082
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 10 Jun 2021 08:00:15
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
User entered 'VISIT3'	System	02 Oct 2020 12:53:38

US3522082

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:00:15

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 00:26:57
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 12:48:59

US3522082

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:00:15

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 00:26:57
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 17:06:52
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	02 Oct 2020 12:52:57
User entered '2 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Oct 2020 12:52:57
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	02 Oct 2020 12:48:59
User entered '2 Nov 2020'	(b) (4), (b) (6)	02 Oct 2020 12:48:59

US3522082

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:00:15

Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 00:26:57
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 17:06:52
User entered '08:26'	(b) (4), (b) (6)	02 Oct 2020 12:48:59

US3522082

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:00:15

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
User entered '2 Oct 2020 08:26'	System	02 Oct 2020 12:52:57
User entered '2 Nov 2020 08:26'	System	02 Oct 2020 12:48:59

US3522082

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:00:15

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 00:26:57
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
User entered '97.0' F	(b) (4) (b) (4), (b) (6)	02 Oct 2020 12:48:59

US3522082

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:00:15

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 00:26:57
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 17:06:52
User entered 'Other (Other)'	(b) (4), (b) (6)	02 Oct 2020 12:48:59

US3522082
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 08:00:15
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 00:26:57
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 17:06:52
User entered 'temporal'	(b) (4), (b) (6)	02 Oct 2020 12:48:59

US3522082

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:00:15

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 00:26:57
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
User entered '77'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 12:48:59

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
User entered 'bpm'	System	02 Oct 2020 12:48:59

US3522082

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:00:15

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 00:26:57
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
User entered '18'	(b) (4), (b) (6)	02 Oct 2020 12:48:59

US3522082

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:00:15

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
User entered 'breaths/min'	System	02 Oct 2020 12:48:59

US3522082

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:00:15

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 00:26:57
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 17:06:52
User entered '135'	(b) (4), (b) (6)	02 Oct 2020 12:48:59

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
User entered 'mmHg'	System	02 Oct 2020 12:48:59

FDA-CBER-2022-1614-0812423

US3522082

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:00:15

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 00:26:57
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 17:06:52
User entered '77'	(b) (4), (b) (6)	02 Oct 2020 12:48:59

US3522082
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 08:00:15
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
User entered 'mmHg'	System	02 Oct 2020 12:48:59

US3522082
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 08:00:15

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48

US3522082

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:00:15

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:00:15

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 00:27:00
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 12:49:42

US3522082

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:00:15

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 00:27:00
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
User entered '2 Oct 2020'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 12:49:42

US3522082

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:00:15

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 00:27:04
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Oct 2020 12:50:07

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:00:15

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 00:27:04
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
User entered '2 Oct 2020'	(b) (4), (b) (6)	02 Oct 2020 12:50:07

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:00:15

Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 00:27:04
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 17:06:52
User entered '08:40'	(b) (4), (b) (6)	02 Oct 2020 12:50:07

US3522082

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:00:15

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
User entered '2 Oct 2020 08:40'	System	02 Oct 2020 12:50:07

US3522082

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:00:15

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 00:27:07
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 17:06:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 12:50:13

US3522082
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 10 Jun 2021 08:00:15
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
User entered '1'	System	02 Oct 2020 12:50:13

US3522082
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
Data entry locked.	System	11 Aug 2020 19:01:01
User entered 'Day 64'	System	11 Aug 2020 19:01:01

US3522082

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-10-12T10:19:13', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'f812cacc-7610-4caf-a0d4-bb020ea61589'	System	12 Oct 2020 14:20:02
User entered 'No (N)'	System	12 Oct 2020 14:20:02

US3522082

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Have you been exposed to someone with 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 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-10-12T10:19:31', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'f812cacc-7610-4caf-a0d4-bb020ea61589'	System	12 Oct 2020 14:20:02
User entered 'No (N)'	System	12 Oct 2020 14:20:02

US3522082

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-10-12T10:19:57', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'f812cacc-7610-4caf-a0d4-bb020ea61589'	System	12 Oct 2020 14:20:02
User entered '12 Oct 2020 10:19:57'	System	12 Oct 2020 14:20:02

US3522082

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
Data entry locked.	System	11 Aug 2020 19:01:01
User entered '11 Oct 2020 00:01'	System	11 Aug 2020 19:01:01

US3522082

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
Data entry locked.	System	11 Aug 2020 19:01:01
User entered '15 Oct 2020 23:59'	System	11 Aug 2020 19:01:01

US3522082
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
Data entry locked.	System	11 Aug 2020 19:01:01
User entered 'Day 71'	System	11 Aug 2020 19:01:01

US3522082

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-10-18T08:24:51', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '2d2766c4-9a6f-4eaa-81fb-5d09904c4da6'	System	18 Oct 2020 12:25:39
User entered 'No (N)'	System	18 Oct 2020 12:25:39

US3522082

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Have you been exposed to someone with 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 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-10-18T08:25:05', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '2d2766c4-9a6f-4eaa-81fb-5d09904c4da6'	System	18 Oct 2020 12:25:39
User entered 'No (N)'	System	18 Oct 2020 12:25:39

US3522082

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-10-18T08:25:35', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '2d2766c4-9a6f-4eaa-81fb-5d09904c4da6'	System	18 Oct 2020 12:25:39
User entered '18 Oct 2020 08:25:35'	System	18 Oct 2020 12:25:39

US3522082

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
Data entry locked.	System	11 Aug 2020 19:01:01
User entered '18 Oct 2020 00:01'	System	11 Aug 2020 19:01:01

US3522082

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
Data entry locked.	System	11 Aug 2020 19:01:01
User entered '22 Oct 2020 23:59'	System	11 Aug 2020 19:01:01

US3522082

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
Data entry locked.	System	11 Aug 2020 19:01:01
User entered 'Day 78'	System	11 Aug 2020 19:01:01

US3522082

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-10-25T09:59:04', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '9f9aa07e-bb0e-4ec9-b196-462b8fad898d'	System	25 Oct 2020 13:59:25
User entered 'No (N)'	System	25 Oct 2020 13:59:25

US3522082

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Have you been exposed to someone with 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 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-10-25T09:59:11', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '9f9aa07e-bb0e-4ec9-b196-462b8fad898d'	System	25 Oct 2020 13:59:25
User entered 'No (N)'	System	25 Oct 2020 13:59:25

US3522082

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-10-25T09:59:21', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '9f9aa07e-bb0e-4ec9-b196-462b8fad898d'	System	25 Oct 2020 13:59:25
User entered '25 Oct 2020 09:59:21'	System	25 Oct 2020 13:59:25

US3522082

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
Data entry locked.	System	11 Aug 2020 19:01:01
User entered '25 Oct 2020 00:01'	System	11 Aug 2020 19:01:01

US3522082

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
Data entry locked.	System	11 Aug 2020 19:01:01
User entered '29 Oct 2020 23:59'	System	11 Aug 2020 19:01:01

US3522082
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
Data entry locked.	System	11 Aug 2020 19:01:01
User entered 'Day 92'	System	11 Aug 2020 19:01:01

US3522082

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-11-08T00:48:18', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '10f04b61-43e6-45c9-bfb2-f98ab72aa373'	System	08 Nov 2020 05:49:46
User entered 'No (N)'	System	08 Nov 2020 05:49:46

US3522082

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Have you been exposed to someone with 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 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-11-08T00:48:58', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '10f04b61-43e6-45c9-bfb2-f98ab72aa373'	System	08 Nov 2020 05:49:46
User entered 'No (N)'	System	08 Nov 2020 05:49:46

US3522082

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-11-08T00:49:39', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '10f04b61-43e6-45c9-bfb2-f98ab72aa373'	System	08 Nov 2020 05:49:46
User entered '08 Nov 2020 00:49:39'	System	08 Nov 2020 05:49:46

US3522082

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
Data entry locked.	System	11 Aug 2020 19:01:01
User entered '08 Nov 2020 00:01'	System	11 Aug 2020 19:01:01

US3522082

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
Data entry locked.	System	11 Aug 2020 19:01:01
User entered '12 Nov 2020 23:59'	System	11 Aug 2020 19:01:01

US3522082
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
Data entry locked.	System	11 Aug 2020 19:01:01
User entered 'Day 99'	System	11 Aug 2020 19:01:01

US3522082

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-11-15T09:29:04', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '6b62961a-fe64-4f3f-9ab4-8850635f3005'	System	15 Nov 2020 14:29:23
User entered 'No (N)'	System	15 Nov 2020 14:29:23

US3522082

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Have you been exposed to someone with 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 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-11-15T09:29:10', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '6b62961a-fe64-4f3f-9ab4-8850635f3005'	System	15 Nov 2020 14:29:23
User entered 'No (N)'	System	15 Nov 2020 14:29:23

US3522082

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-11-15T09:29:20', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '6b62961a-fe64-4f3f-9ab4-8850635f3005'	System	15 Nov 2020 14:29:23
User entered '15 Nov 2020 09:29:20'	System	15 Nov 2020 14:29:23

US3522082

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
Data entry locked.	System	11 Aug 2020 19:01:01
User entered '15 Nov 2020 00:01'	System	11 Aug 2020 19:01:01

US3522082

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 08:58:31
Data entry locked.	System	11 Aug 2020 19:01:01
User entered '19 Nov 2020 23:59'	System	11 Aug 2020 19:01:01

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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 (72ce58df7ebdb318)', Time: '2020-11-19T17:52:13', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '5b843003-24b6-4339-98b1-fe60da0e30b1'	System	19 Nov 2020 22:52:37
User entered 'No (N)'	System	19 Nov 2020 22:52:37

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15

Have you been exposed to someone with 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 (72ce58df7ebdb318)', Time: '2020-11-19T17:52:20', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '5b843003-24b6-4339-98b1-fe60da0e30b1'	System	19 Nov 2020 22:52:37
User entered 'No (N)'	System	19 Nov 2020 22:52:37

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-11-19T17:52:29', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '5b843003-24b6-4339-98b1-fe60da0e30b1'	System	19 Nov 2020 22:52:37
User entered '19 Nov 2020 17:52:29'	System	19 Nov 2020 22:52:37

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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 (72ce58df7ebdb318)', Time: '2020-11-27T18:26:11', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '0c0d67f0-eb2d-4f56-8481-81ca9a2527f1'	System	27 Nov 2020 23:26:54
User entered 'No (N)'	System	27 Nov 2020 23:26:54

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Have you been exposed to someone with 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 (72ce58df7ebdb318)', Time: '2020-11-27T18:26:31', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '0c0d67f0-eb2d-4f56-8481-81ca9a2527f1'	System	27 Nov 2020 23:26:54
User entered 'No (N)'	System	27 Nov 2020 23:26:54

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-11-27T18:26:50', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '0c0d67f0-eb2d-4f56-8481-81ca9a2527f1'	System	27 Nov 2020 23:26:54
User entered '27 Nov 2020 18:26:50'	System	27 Nov 2020 23:26:54

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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 (72ce58df7ebdb318)', Time: '2020-12-03T18:23:34', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'a446c129-c0ee-4acc-b3aa-e7c65bdc6a8a'	System	03 Dec 2020 23:23:54
User entered 'No (N)'	System	03 Dec 2020 23:23:54

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Have you been exposed to someone with 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 (72ce58df7ebdb318)', Time: '2020-12-03T18:23:39', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'a446c129-c0ee-4acc-b3aa-e7c65bdc6a8a'	System	03 Dec 2020 23:23:54
User entered 'No (N)'	System	03 Dec 2020 23:23:54

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-12-03T18:23:50', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'a446c129-c0ee-4acc-b3aa-e7c65bdc6a8a'	System	03 Dec 2020 23:23:54
User entered '03 Dec 2020 18:23:50'	System	03 Dec 2020 23:23:54

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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 (72ce58df7ebdb318)', Time: '2020-12-10T09:34:11', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'c0e86cb1-2563-421f-bdb5-887a313aa98f'	System	10 Dec 2020 14:35:12
User entered 'No (N)'	System	10 Dec 2020 14:35:12

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Have you been exposed to someone with 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 (72ce58df7ebdb318)', Time: '2020-12-10T09:34:50', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'c0e86cb1-2563-421f-bdb5-887a313aa98f'	System	10 Dec 2020 14:35:12
User entered 'No (N)'	System	10 Dec 2020 14:35:12

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-12-10T09:35:07', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'c0e86cb1-2563-421f-bdb5-887a313aa98f'	System	10 Dec 2020 14:35:12
User entered '10 Dec 2020 09:35:07'	System	10 Dec 2020 14:35:12

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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 (72ce58df7ebdb318)', Time: '2020-12-17T00:03:23', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '7396b214-590e-4fa2-a262-80ee82d7e5aa'	System	17 Dec 2020 05:04:21
User entered 'No (N)'	System	17 Dec 2020 05:04:21

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Have you been exposed to someone with 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 (72ce58df7ebdb318)', Time: '2020-12-17T00:03:50', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '7396b214-590e-4fa2-a262-80ee82d7e5aa'	System	17 Dec 2020 05:04:21
User entered 'No (N)'	System	17 Dec 2020 05:04:21

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-12-17T00:04:18', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '7396b214-590e-4fa2-a262-80ee82d7e5aa'	System	17 Dec 2020 05:04:21
User entered '17 Dec 2020 00:04:18'	System	17 Dec 2020 05:04:21

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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 (72ce58df7ebdb318)', Time: '2020-12-28T16:25:33', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'dc3cda49-13be-4986-aaf3-8b3787463096'	System	28 Dec 2020 21:25:58
User entered 'No (N)'	System	28 Dec 2020 21:25:58

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Have you been exposed to someone with 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 (72ce58df7ebdb318)', Time: '2020-12-28T16:25:46', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'dc3cda49-13be-4986-aaf3-8b3787463096'	System	28 Dec 2020 21:25:58
User entered 'No (N)'	System	28 Dec 2020 21:25:58

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-12-28T16:25:54', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'dc3cda49-13be-4986-aaf3-8b3787463096'	System	28 Dec 2020 21:25:58
User entered '28 Dec 2020 16:25:54'	System	28 Dec 2020 21:25:58

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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 (72ce58df7ebdb318)', Time: '2020-12-31T15:39:49', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '453d5f8d-acf5-41e0-965b-401d1a53842f'	System	31 Dec 2020 20:40:30
User entered 'No (N)'	System	31 Dec 2020 20:40:30

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Have you been exposed to someone with 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 (72ce58df7ebdb318)', Time: '2020-12-31T15:40:17', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '453d5f8d-acf5-41e0-965b-401d1a53842f'	System	31 Dec 2020 20:40:30
User entered 'No (N)'	System	31 Dec 2020 20:40:30

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2020-12-31T15:40:25', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '453d5f8d-acf5-41e0-965b-401d1a53842f'	System	31 Dec 2020 20:40:30
User entered '31 Dec 2020 15:40:25'	System	31 Dec 2020 20:40:30

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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 (72ce58df7ebdb318)', Time: '2021-01-08T14:50:54', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '780fa1c9-667b-4808-a114-883f8774664b'	System	08 Jan 2021 19:51:16
User entered 'No (N)'	System	08 Jan 2021 19:51:16

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Have you been exposed to someone with 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 (72ce58df7ebdb318)', Time: '2021-01-08T14:51:03', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '780fa1c9-667b-4808-a114-883f8774664b'	System	08 Jan 2021 19:51:16
User entered 'No (N)'	System	08 Jan 2021 19:51:16

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2021-01-08T14:51:11', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '780fa1c9-667b-4808-a114-883f8774664b'	System	08 Jan 2021 19:51:16
User entered '08 Jan 2021 14:51:11'	System	08 Jan 2021 19:51:16

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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 (72ce58df7ebdb318)', Time: '2021-01-14T22:08:18', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'a0a0d896-7188-4024-808d-f7ad79f0f316'	System	15 Jan 2021 03:08:37
User entered 'No (N)'	System	15 Jan 2021 03:08:37

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Have you been exposed to someone with 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 (72ce58df7ebdb318)', Time: '2021-01-14T22:08:28', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'a0a0d896-7188-4024-808d-f7ad79f0f316'	System	15 Jan 2021 03:08:37
User entered 'No (N)'	System	15 Jan 2021 03:08:37

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2021-01-14T22:08:32', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'a0a0d896-7188-4024-808d-f7ad79f0f316'	System	15 Jan 2021 03:08:37
User entered '14 Jan 2021 22:08:32'	System	15 Jan 2021 03:08:37

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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 (72ce58df7ebdb318)', Time: '2021-01-21T14:46:53', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'f6c0b549-9d2c-4c72-9a56-425c187e330b'	System	21 Jan 2021 19:47:08
User entered 'No (N)'	System	21 Jan 2021 19:47:08

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Have you been exposed to someone with 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 (72ce58df7ebdb318)', Time: '2021-01-21T14:46:58', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'f6c0b549-9d2c-4c72-9a56-425c187e330b'	System	21 Jan 2021 19:47:08
User entered 'No (N)'	System	21 Jan 2021 19:47:08

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2021-01-21T14:47:03', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'f6c0b549-9d2c-4c72-9a56-425c187e330b'	System	21 Jan 2021 19:47:08
User entered '21 Jan 2021 14:47:03'	System	21 Jan 2021 19:47:08

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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 (72ce58df7ebdb318)', Time: '2021-01-28T11:31:42', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '340718a3-5eb8-4488-bd03-03921cc1aeae'	System	28 Jan 2021 16:32:18
User entered 'No (N)'	System	28 Jan 2021 16:32:18

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Have you been exposed to someone with 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 (72ce58df7ebdb318)', Time: '2021-01-28T11:31:59', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '340718a3-5eb8-4488-bd03-03921cc1aeae'	System	28 Jan 2021 16:32:18
User entered 'No (N)'	System	28 Jan 2021 16:32:18

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2021-01-28T11:32:14', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '340718a3-5eb8-4488-bd03-03921cc1aeae'	System	28 Jan 2021 16:32:18
User entered '28 Jan 2021 11:32:14'	System	28 Jan 2021 16:32:18

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 03:55:43

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 03:55:43

FDA-CBER-2022-1614-0812531

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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 (72ce58df7ebdb318)', Time: '2021-02-04T12:54:23', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '58fab43f-48d2-4ae4-9358-fb5d4dff9cb4'	System	04 Feb 2021 17:55:17
User entered 'No (N)'	System	04 Feb 2021 17:55:17

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Have you been exposed to someone with 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 (72ce58df7ebdb318)', Time: '2021-02-04T12:54:26', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '58fab43f-48d2-4ae4-9358-fb5d4dff9cb4'	System	04 Feb 2021 17:55:17
User entered 'No (N)'	System	04 Feb 2021 17:55:17

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2021-02-04T12:54:29', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '58fab43f-48d2-4ae4-9358-fb5d4dff9cb4'	System	04 Feb 2021 17:55:17
User entered '04 Feb 2021 12:54:29'	System	04 Feb 2021 17:55:17

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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 (72ce58df7ebdb318)', Time: '2021-02-11T08:42:05', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '0a72373a-9101-41c3-816a-86d2b3f9254c'	System	11 Feb 2021 13:42:30
User entered 'No (N)'	System	11 Feb 2021 13:42:30

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Have you been exposed to someone with 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 (72ce58df7ebdb318)', Time: '2021-02-11T08:42:11', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '0a72373a-9101-41c3-816a-86d2b3f9254c'	System	11 Feb 2021 13:42:30
User entered 'No (N)'	System	11 Feb 2021 13:42:30

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2021-02-11T08:42:18', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '0a72373a-9101-41c3-816a-86d2b3f9254c'	System	11 Feb 2021 13:42:30
User entered '11 Feb 2021 08:42:18'	System	11 Feb 2021 13:42:30

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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 (72ce58df7ebdb318)', Time: '2021-02-18T02:36:41', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '6af8d7a5-2d60-4430-bc4b-18ab30c8707a'	System	18 Feb 2021 07:36:54
User entered 'No (N)'	System	18 Feb 2021 07:36:54

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Have you been exposed to someone with 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 (72ce58df7ebdb318)', Time: '2021-02-18T02:36:47', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '6af8d7a5-2d60-4430-bc4b-18ab30c8707a'	System	18 Feb 2021 07:36:54
User entered 'No (N)'	System	18 Feb 2021 07:36:54

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2021-02-18T02:36:51', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '6af8d7a5-2d60-4430-bc4b-18ab30c8707a'	System	18 Feb 2021 07:36:54
User entered '18 Feb 2021 02:36:51'	System	18 Feb 2021 07:36:54

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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 (72ce58df7ebdb318)', Time: '2021-02-25T14:59:46', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'e4f031d0-69a3-4b60-81c3-45fdd7db108a'	System	25 Feb 2021 19:59:57
User entered 'No (N)'	System	25 Feb 2021 19:59:57

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Have you been exposed to someone with 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 (72ce58df7ebdb318)', Time: '2021-02-25T14:59:38', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'e4f031d0-69a3-4b60-81c3-45fdd7db108a'	System	25 Feb 2021 19:59:57
User entered 'No (N)'	System	25 Feb 2021 19:59:57

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2021-02-25T14:59:49', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'e4f031d0-69a3-4b60-81c3-45fdd7db108a'	System	25 Feb 2021 19:59:57
User entered '25 Feb 2021 14:59:49'	System	25 Feb 2021 19:59:57

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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 (72ce58df7ebdb318)', Time: '2021-03-04T01:14:48', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'bd57e6a9-7efa-43e4-94c1-f1a014860352'	System	04 Mar 2021 06:15:39
User entered 'No (N)'	System	04 Mar 2021 06:15:39

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Have you been exposed to someone with 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 (72ce58df7ebdb318)', Time: '2021-03-04T01:15:05', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'bd57e6a9-7efa-43e4-94c1-f1a014860352'	System	04 Mar 2021 06:15:39
User entered 'No (N)'	System	04 Mar 2021 06:15:39

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2021-03-04T01:15:23', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'bd57e6a9-7efa-43e4-94c1-f1a014860352'	System	04 Mar 2021 06:15:39
User entered '04 Mar 2021 01:15:23'	System	04 Mar 2021 06:15:39

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 03:55:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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 (72ce58df7ebdb318)', Time: '2021-03-11T12:53:51', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '3fe0f21e-14e1-43f7-a916-cefd9724a98d'	System	11 Mar 2021 23:52:57
User entered 'No (N)'	System	11 Mar 2021 23:52:57

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15

Have you been exposed to someone with 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 (72ce58df7ebdb318)', Time: '2021-03-11T12:53:54', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '3fe0f21e-14e1-43f7-a916-cefd9724a98d'	System	11 Mar 2021 23:52:57
User entered 'No (N)'	System	11 Mar 2021 23:52:57

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2021-03-11T12:53:58', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '3fe0f21e-14e1-43f7-a916-cefd9724a98d'	System	11 Mar 2021 23:52:57
User entered '11 Mar 2021 12:53:58'	System	11 Mar 2021 23:52:57

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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 (72ce58df7ebdb318)', Time: '2021-03-18T01:13:42', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'f2e907d1-156c-41cb-a990-66d64a4f5b8c'	System	18 Mar 2021 05:14:14
User entered 'No (N)'	System	18 Mar 2021 05:14:14

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Have you been exposed to someone with 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 (72ce58df7ebdb318)', Time: '2021-03-18T01:14:01', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'f2e907d1-156c-41cb-a990-66d64a4f5b8c'	System	18 Mar 2021 05:14:14
User entered 'No (N)'	System	18 Mar 2021 05:14:14

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2021-03-18T01:14:08', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'f2e907d1-156c-41cb-a990-66d64a4f5b8c'	System	18 Mar 2021 05:14:14
User entered '18 Mar 2021 01:14:08'	System	18 Mar 2021 05:14:14

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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 (72ce58df7ebdb318)', Time: '2021-03-25T17:21:10', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'bfe9a4a9-9e43-42a9-9786-54c80fcc62fd'	System	25 Mar 2021 21:21:27
User entered 'No (N)'	System	25 Mar 2021 21:21:27

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15

Have you been exposed to someone with 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 (72ce58df7ebdb318)', Time: '2021-03-25T17:21:18', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'bfe9a4a9-9e43-42a9-9786-54c80fcc62fd'	System	25 Mar 2021 21:21:27
User entered 'No (N)'	System	25 Mar 2021 21:21:27

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2021-03-25T17:21:22', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'bfe9a4a9-9e43-42a9-9786-54c80fcc62fd'	System	25 Mar 2021 21:21:27
User entered '25 Mar 2021 17:21:22'	System	25 Mar 2021 21:21:27

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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 (72ce58df7ebdb318)', Time: '2021-04-05T09:54:32-04:00', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'e7859c8a-6d74-41f9-8804-e291686cc268'	System	05 Apr 2021 13:54:55
User entered 'No (N)'	System	05 Apr 2021 13:54:55

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Have you been exposed to someone with 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 (72ce58df7ebdb318)', Time: '2021-04-05T09:54:47-04:00', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'e7859c8a-6d74-41f9-8804-e291686cc268'	System	05 Apr 2021 13:54:55
User entered 'No (N)'	System	05 Apr 2021 13:54:55

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2021-04-05T09:54:52-04:00', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'e7859c8a-6d74-41f9-8804-e291686cc268'	System	05 Apr 2021 13:54:55
User entered '05 Apr 2021 09:54:52'	System	05 Apr 2021 13:54:55

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 03:55:43

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 03:55:43

FDA-CBER-2022-1614-0812586

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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 (72ce58df7ebdb318)', Time: '2021-04-08T00:31:58-04:00', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '931e3222-944c-43c1-afb0-8a1b62cbbb76'	System	08 Apr 2021 04:32:12
User entered 'No (N)'	System	08 Apr 2021 04:32:12

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Have you been exposed to someone with 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 (72ce58df7ebdb318)', Time: '2021-04-08T00:32:04-04:00', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '931e3222-944c-43c1-afb0-8a1b62cbbb76'	System	08 Apr 2021 04:32:12
User entered 'No (N)'	System	08 Apr 2021 04:32:12

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2021-04-08T00:32:08-04:00', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '931e3222-944c-43c1-afb0-8a1b62cbbb76'	System	08 Apr 2021 04:32:12
User entered '08 Apr 2021 00:32:08'	System	08 Apr 2021 04:32:12

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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 (72ce58df7ebdb318)', Time: '2021-04-15T06:41:23-04:00', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '6dd43bee-e2d1-40f0-a3a8-cdadf8e5edd4'	System	15 Apr 2021 10:41:40
User entered 'No (N)'	System	15 Apr 2021 10:41:40

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Have you been exposed to someone with 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 (72ce58df7ebdb318)', Time: '2021-04-15T06:41:31-04:00', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '6dd43bee-e2d1-40f0-a3a8-cdadf8e5edd4'	System	15 Apr 2021 10:41:40
User entered 'No (N)'	System	15 Apr 2021 10:41:40

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2021-04-15T06:41:36-04:00', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '6dd43bee-e2d1-40f0-a3a8-cdadf8e5edd4'	System	15 Apr 2021 10:41:40
User entered '15 Apr 2021 06:41:36'	System	15 Apr 2021 10:41:40

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 03:55:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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 (72ce58df7ebdb318)', Time: '2021-04-23T14:07:58-04:00', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'a9d1e7f8-c16d-456b-8bc2-19cafbc00c35'	System	23 Apr 2021 18:08:10
User entered 'No (N)'	System	23 Apr 2021 18:08:10

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Have you been exposed to someone with 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 (72ce58df7ebdb318)', Time: '2021-04-23T14:08:02-04:00', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'a9d1e7f8-c16d-456b-8bc2-19cafbc00c35'	System	23 Apr 2021 18:08:10
User entered 'No (N)'	System	23 Apr 2021 18:08:10

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2021-04-23T14:08:06-04:00', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'a9d1e7f8-c16d-456b-8bc2-19cafbc00c35'	System	23 Apr 2021 18:08:10
User entered '23 Apr 2021 14:08:06'	System	23 Apr 2021 18:08:10

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

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 (72ce58df7ebdb318)', Time: '2021-04-30T13:27:37-04:00', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'faa99858-29e8-43f5-aeb4-be25e89dcc99'	System	30 Apr 2021 17:27:52
User entered 'No (N)'	System	30 Apr 2021 17:27:52

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Have you been exposed to someone with 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 (72ce58df7ebdb318)', Time: '2021-04-30T13:27:40-04:00', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'faa99858-29e8-43f5-aeb4-be25e89dcc99'	System	30 Apr 2021 17:27:52
User entered 'No (N)'	System	30 Apr 2021 17:27:52

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2021-04-30T13:27:44-04:00', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: 'faa99858-29e8-43f5-aeb4-be25e89dcc99'	System	30 Apr 2021 17:27:52
User entered '30 Apr 2021 13:27:44'	System	30 Apr 2021 17:27:52

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 03:55:43

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 03:55:43

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 03:55:43

FDA-CBER-2022-1614-0812634

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 03:55:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 03:55:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 03:55:43

FDA-CBER-2022-1614-0812688

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 03:55:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 03:55:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 03:55:43

FDA-CBER-2022-1614-0812719

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 03:55:43

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 03:55:43

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 03:55:43

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 03:55:43

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 03:55:43

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 03:55:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 03:55:43

FDA-CBER-2022-1614-0812784

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 03:55:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 03:55:43

FDA-CBER-2022-1614-0812789

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 03:55:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 03:55:43

FDA-CBER-2022-1614-0812798

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 03:55:43

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 03:55:43

FDA-CBER-2022-1614-0812804

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 03:55:43

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 03:55:43

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '06 Oct 2022 00:01'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '10 Oct 2022 23:59'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 03:55:43

US3522082

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:00:15

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '13 Oct 2022 00:01'	System	19 Nov 2020 03:55:43

US3522082
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 08:00:15
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:55:43
Amendment Manager: User entered '17 Oct 2022 23:59'	System	19 Nov 2020 03:55:43

FDA-CBER-2022-1614-0812837

US3522082

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:00:15

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)	24 Apr 2021 19:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2021-02-27T19:44:38', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '1f017e04-822d-4664-8521-832e493add17'	System	28 Feb 2021 00:45:31
User entered 'No (N)'	System	28 Feb 2021 00:45:31

US3522082

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:00:15

Date & Time of Submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:54:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72ce58df7ebdb318)', Time: '2021-02-27T19:45:27', User OID: 'PatientReportedOutcome (US3522082)', ODM File OID: '1f017e04-822d-4664-8521-832e493add17'	System	28 Feb 2021 00:45:31
User entered '27 Feb 2021 19:45:27'	System	28 Feb 2021 00:45:31

US3522082

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:00:15

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:54:24
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:20:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:55:19

US3522082

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:00:15

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:54:24
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:20:17
User entered '4 Nov 2020' reason for change: New Information	(b) (4) (b) (4), (b) (6)	04 Nov 2020 14:11:20
User entered '3 Nov 2020'	(b) (4), (b) (6)	03 Nov 2020 19:55:19

US3522082

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:00:15

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:54:24
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:20:17
User entered 'Contact Made (CONTACT MADE)' reason for change: New Information	(b) (4) (b) (4), (b) (6)	04 Nov 2020 14:11:20
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4), (b) (6)	03 Nov 2020 19:55:19

US3522082
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 10 Jun 2021 08:00:15
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:54:24
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
User entered '"No ongoing or new AE reported, no new illness or hospital visits; no changes in health status, medications, Covid-19 exposure or pregnancy risk."' reason for change: New Information	(b) (4), (b) (6)	04 Nov 2020 14:11:20
User entered 'Called, no answer, left VM'	(b) (4), (b) (6)	03 Nov 2020 19:55:19

US3522082

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:00:15

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:54:30
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Nov 2020 14:11:24

US3522082
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 10 Jun 2021 08:00:15
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:20:48
User entered '1'	System	04 Nov 2020 14:11:24

US3522082

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:00:15

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:27:05
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:54:39
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Dec 2020 19:16:24

US3522082
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 10 Jun 2021 08:00:15

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:27:05
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:54:39
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
User entered '8 Dec 2020' reason for change: New Information	Yaman Ahmed (b) (4) (b) (4)	08 Dec 2020 23:06:15
User entered '07 Dec 2020'	(b) (4), (b) (6)	07 Dec 2020 19:16:24

US3522082

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:00:15

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:27:05
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:54:39
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:20:17
User entered 'Contact Made (CONTACT MADE)' reason for change: New Information	Yaman Ahmed (b) (4)	08 Dec 2020 23:06:15
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4), (b) (6)	07 Dec 2020 19:16:24

US3522082

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:00:15

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:27:05
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:54:39
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
User entered 'No ongoing or new AE reported, no new illness or hospital visits; no changes in health status, medications, Covid-19 exposure' reason for change: New Information	Yaman Ahmed (b) (4) (b) (4)	08 Dec 2020 23:06:15
User entered 'VM left'	(b) (4), (b) (6)	07 Dec 2020 19:16:24

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US3522082

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:00:15

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:27:05
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:54:42
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
User entered 'Yes (Y)'	Yaman Ahmed (b) (4) (b) (4)	08 Dec 2020 23:06:19

US3522082
Folder: Safety Call Day 119 (1)
Form: Continuing
Generated On: 10 Jun 2021 08:00:15
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:27:05
User entered '1'	System	08 Dec 2020 23:06:19

US3522082

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:00:15

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:27:05
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:54:52
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
User entered 'Yes (Y)'	Yaman Ahmed (b) (4) (b) (4)	06 Jan 2021 14:47:56

US3522082

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:00:15

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:27:05
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:54:52
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
User entered '6 Jan 2021'	Yaman Ahmed (b) (4) (b) (4)	06 Jan 2021 14:47:56

US3522082

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:00:15

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:27:05
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:54:52
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
User entered 'Contact Made (CONTACT MADE)'	Yaman Ahmed (b) (4) (b) (4)	06 Jan 2021 14:47:56

US3522082

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:00:15

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:27:05
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:54:52
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
User entered 'No ongoing or new AE reported, no new illness or hospital visits; no changes in health status, medications, Covid-19 exposure'	Yaman Ahmed (b) (4) (b) (4)	06 Jan 2021 14:47:56

US3522082

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:00:15

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:27:05
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:54:55
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
User entered 'Yes (Y)'	Yaman Ahmed (b) (4) (b) (4)	06 Jan 2021 14:48:01

US3522082
Folder: Safety Call Day 149 (1)
Form: Continuing
Generated On: 10 Jun 2021 08:00:15
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:27:05
User entered '1'	System	06 Jan 2021 14:48:01

US3522082

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:00:15

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:27:05
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:55:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
User entered 'Yes (Y)'	Yaman Ahmed (b) (4) (b) (4)	04 Feb 2021 16:49:24

US3522082

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:00:15

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:27:05
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:55:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
User entered '4 Feb 2021'	Yaman Ahmed (b) (4) (b) (4)	04 Feb 2021 16:49:24

US3522082

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:00:15

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:27:05
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:55:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
User entered 'Contact Made (CONTACT MADE)' reason for change: New Information	Yaman Ahmed (b) (4) (b) (4)	04 Feb 2021 17:19:43
User entered 'Contact Not Made (CONTACT NOT MADE)'	Yaman Ahmed (b) (4) (b) (4)	04 Feb 2021 16:49:24

US3522082

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:00:15

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:27:05
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:55:37
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
User entered 'Has an ICD implant with a monitor and cardiologist called him yesterday to inform him that his heart beat was not normal (skipping); he also told her that he had chest pain last night' reason for change: New Information	Yaman Ahmed (b) (4) (b) (4)	04 Feb 2021 17:19:43
User entered 'left a voicemail'	Yaman Ahmed (b) (4) (b) (4)	04 Feb 2021 16:49:24

US3522082

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:00:15

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:27:05
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:55:39
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
User entered 'Yes (Y)'	Yaman Ahmed (b) (4) (b) (4)	04 Feb 2021 17:19:56

US3522082
Folder: Safety Call Day 179 (1)
Form: Continuing
Generated On: 10 Jun 2021 08:00:15
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:27:05
User entered '1'	System	04 Feb 2021 17:19:56

US3522082

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:00:15

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:29:20
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:56:37
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Mar 2021 14:55:43

US3522082
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 10 Jun 2021 08:00:15

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:29:20
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:56:37
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:28
User entered '8 Mar 2021'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 14:55:43

US3522082

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:00:15

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 02:29:20
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:56:37
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:28
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 14:55:43

US3522082
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 10 Jun 2021 08:00:15
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:29:20
User entered 'VISIT4'	System	08 Mar 2021 14:55:43

US3522082

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:00:15

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:29:20
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:56:43
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	01 Apr 2021 18:54:15
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	30 Mar 2021 18:43:10

US3522082
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 08:00:15
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:29:20
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:56:43
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	01 Apr 2021 18:54:15
User entered empty.	Sharon Mathys (b) (4) (b) (4)	30 Mar 2021 18:43:10

US3522082
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 08:00:15

Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:29:20
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:56:43
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	01 Apr 2021 18:54:15
User entered empty.	Sharon Mathys (b) (4) (b) (4)	30 Mar 2021 18:43:10

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:29:20
User entered empty.	System	30 Mar 2021 18:43:10

FDA-CBER-2022-1614-0812871

US3522082

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:00:15

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:29:20
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:56:43
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	01 Apr 2021 18:54:15
User entered empty.	Sharon Mathys (b) (4) (b) (4)	30 Mar 2021 18:43:10

US3522082
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 08:00:15

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:29:20
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:56:43
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	01 Apr 2021 18:54:15
User entered empty.	Sharon Mathys (b) (4) (b) (4)	30 Mar 2021 18:43:10

US3522082

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:00:15

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:29:20
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:56:43
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	01 Apr 2021 18:54:15
User entered empty.	Sharon Mathys (b) (4) (b) (4)	30 Mar 2021 18:43:10

Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 08:00:15
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:29:20
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:56:43
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	01 Apr 2021 18:54:15
User entered empty.	Sharon Mathys (b) (4) (b) (4)	30 Mar 2021 18:43:10

US3522082
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 08:00:15
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:29:20
User entered empty.	System	30 Mar 2021 18:43:10

US3522082
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 08:00:15
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:29:20
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:56:43
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	01 Apr 2021 18:54:15
User entered empty.	Sharon Mathys (b) (4) (b) (4)	30 Mar 2021 18:43:10

US3522082
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 08:00:15
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:29:20
User entered empty.	System	30 Mar 2021 18:43:10

US3522082

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:00:15

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:29:20
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:56:43
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	01 Apr 2021 18:54:15
User entered empty.	Sharon Mathys (b) (4) (b) (4)	30 Mar 2021 18:43:10

US3522082
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 08:00:15
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:29:20
User entered empty.	System	30 Mar 2021 18:43:10

US3522082
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 08:00:15
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:29:20
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:56:43
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	01 Apr 2021 18:54:15
User entered empty.	Sharon Mathys (b) (4) (b) (4)	30 Mar 2021 18:43:10

US3522082
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 08:00:15
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:29:20
User entered empty.	System	30 Mar 2021 18:43:10

US3522082

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:00:15

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:29:20

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:29:20

Folder: Visit 4 Day 209 (1)
Form: Physical Examination
Generated On: 10 Jun 2021 08:00:15

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:29:20
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:57:13
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 14:55:57

FDA-CBER-2022-1614-0812885

US3522082

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:00:15

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:29:20
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:57:13
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:28
User entered '8 Mar 2021'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 14:55:57

US3522082

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:00:15

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:29:20
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:57:17
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 15:04:00

US3522082

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:00:15

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:29:20
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:57:17
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:28
User entered '8 Mar 2021'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 15:04:00

US3522082

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:00:15

Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:29:20
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:57:17
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:28
User entered '10:02'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 15:04:00

US3522082

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:00:15

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:29:20
User entered '8 Mar 2021 10:02'	System	08 Mar 2021 15:04:00

US3522082

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:00:15

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:29:20
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:57:19
User signature succeeded.	Marcus Zervos (b) (4)	09 Mar 2021 15:35:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 15:04:07

US3522082

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:00:15

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:29:20
User entered '1'	System	08 Mar 2021 15:04:07

US3522082

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:00:15

Was Contact Attempted?

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	12 Apr 2021 11:52:25
User entered 'Yes (Y)'	Yaman Ahmed (b) (4) (b) (4)	06 Apr 2021 13:40:35

US3522082

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:00:15

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	12 Apr 2021 11:52:25
User entered '6 Apr 2021'	Yaman Ahmed (b) (4) (b) (4)	06 Apr 2021 13:40:35

US3522082

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:00:15

Please select one status for the follow-up contact

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	12 Apr 2021 11:52:25
User entered 'Contact Made (CONTACT MADE)' reason for change: New Information	Yaman Ahmed (b) (4) (b) (4)	06 Apr 2021 15:37:36
User entered 'Contact Not Made (CONTACT NOT MADE)'	Yaman Ahmed (b) (4) (b) (4)	06 Apr 2021 13:40:35

US3522082

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:00:15

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	12 Apr 2021 11:52:25
User entered 'REPORTS THAT HIS HEALTH IS CURRENTLY STABLE, THOUGH STILL HAS PERSISTENT CHEST CONGESTION, AND IS DUE FOR A PCP FOLLOW UP ON FRIDAY, 09 APR 2021; no other changes reported, no covid-19 exposure' reason for change: New Information	Yaman Ahmed (b) (4) (b) (4)	06 Apr 2021 15:38:03
User entered 'Reports that his health is currently stable, though still has persistent chest congestion (which he says is intermittent and normal for his condition), and is due for a PCP follow up on Friday, 09 Apr 2021' (non-conformant).	Yaman Ahmed (b) (4) (b) (4)	06 Apr 2021 15:37:36
User entered 'left a voicemail message'	Yaman Ahmed (b) (4) (b) (4)	06 Apr 2021 13:40:35

US3522082

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:00:15

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	12 Apr 2021 11:52:25
User entered 'Yes (Y)'	Yaman Ahmed (b) (4) (b) (4)	06 Apr 2021 15:38:11

US3522082

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:00:15

Continuing Flag

Audit	User	Time (GMT)
User entered '1'	System	06 Apr 2021 15:38:11

US3522082

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

Form: Visit Date

Generated On: 10 Jun 2021 08:00:15

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:42:35
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:55:58
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:20:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:00:55

US3522082

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

Form: Visit Date

Generated On: 10 Jun 2021 08:00:15

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:42:35
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:55:58
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:20:17
User entered '28 Jan 2021'	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:00:55

US3522082

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

Form: Visit Date

Generated On: 10 Jun 2021 08:00:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:42:35
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:55:58
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:20:17
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:00:55

US3522082

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

Form: Visit Date

Generated On: 10 Jun 2021 08:00:15

Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:42:35
User entered 'UNBLND_DECIDE'	System	28 Jan 2021 15:00:55

US3522082

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

Form: Unblinding

Generated On: 10 Jun 2021 08:00:15

Date of updated informed consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:42:35
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:56:03
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:20:17
User entered '28 Jan 2021'	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:17:05

US3522082

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

Form: Unblinding

Generated On: 10 Jun 2021 08:00:15

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:42:35
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:56:03
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 18:01:29
User entered '0'	Sharon Mathys (b) (4) (b) (4)	16 Mar 2021 17:57:24
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 04:37:00

US3522082

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

Form: Unblinding

Generated On: 10 Jun 2021 08:00:15

Was the participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:42:35
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:56:03
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:20:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:17:05

US3522082

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

Form: Unblinding

Generated On: 10 Jun 2021 08:00:15

Under what version of the Protocol was the Participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:42:35
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:56:03
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 18:01:29
User entered 'Amendment 6 or later (Amendment 6 or later)'	Sharon Mathys (b) (4) (b) (4)	16 Mar 2021 17:57:24
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 04:37:00

US3522082

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

Form: Unblinding

Generated On: 10 Jun 2021 08:00:15

Date of unblinding *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:42:35
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:56:03
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:20:17
User entered '28 Jan 2021'	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:17:05

US3522082

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

Form: Unblinding

Generated On: 10 Jun 2021 08:00:15

Participant randomization assignment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:42:35
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:56:03
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:20:17
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:17:05

US3522082

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

Form: Unblinding

Generated On: 10 Jun 2021 08:00:15

Actual Dose 1

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:42:35
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:56:03
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:20:17
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:17:05

US3522082

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

Form: Unblinding

Generated On: 10 Jun 2021 08:00:15

Actual Dose 2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:42:35
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:56:03
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:20:17
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:17:05

US3522082

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

Form: Unblinding

Generated On: 10 Jun 2021 08:00:15

Will participant receive mRNA-1273?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:42:35
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:56:03
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:20:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:17:05

US3522082

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

Form: Unblinding

Generated On: 10 Jun 2021 08:00:15

Placebo Only Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:42:35
User entered empty.	System	28 Jan 2021 15:17:05

US3522082

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

Form: Unblinding

Generated On: 10 Jun 2021 08:00:15

Continuing with mRNA-1273

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:42:35
User entered empty.	System	28 Jan 2021 15:17:05

US3522082

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:00:15

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:42:35
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:56:11
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:20:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:36:25

US3522082

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:00:15

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:42:35
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:56:11
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:20:17
User entered '28 Jan 2021'	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:36:25

US3522082

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:00:15

Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:42:35
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:56:11
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:20:17
User entered '10:25'	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:36:25

US3522082

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:00:15

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:42:35
User entered '28 Jan 2021 10:25'	System	28 Jan 2021 15:36:25

US3522082

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:00:15

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:42:35
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:56:16
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:20:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:36:33

US3522082

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:00:15

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:42:35
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:56:16
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:20:17
User entered '28 Jan 2021'	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:36:33

Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 10 Jun 2021 08:00:15
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:42:35
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 21:56:16
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
User entered '10:30'	(b) (4), (b) (6)	28 Jan 2021 15:36:33

US3522082

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:00:15

Collection Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:42:35
User entered '28 Jan 2021 10:30'	System	28 Jan 2021 15:36:33

US3522082

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 08:00:15

Did the participant experience any adverse events?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:48:01
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:00:50
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
User entered 'Yes (Y)'	Yaman Ahmed (b) (4) (b) (4)	04 Feb 2021 17:20:29

US3522082

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:00:15

Adverse event

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User coded data point as SOC: Investigations, HLGT: Cardiac and vascular investigations (excl enzyme tests), HLT: Heart rate and pulse investigations, PT: Heart rate irregular, LLT: Heartbeats irregular - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Feb 2021 17:23:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Feb 2021 17:23:47
Data point term sent to Coder	System	04 Feb 2021 17:22:27
User entered 'irregular heart beat'	Yaman Ahmed (b) (4) (b) (4)	04 Feb 2021 17:22:26

FDA-CBER-2022-1614-0812923

US3522082

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:00:15

Was this a medically-attended AE?

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered 'Yes (Y)'	Yaman Ahmed (b) (4) (b) (4)	04 Feb 2021 17:22:26

US3522082

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:00:15

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered 'No (N)'	Yaman Ahmed (b) (4) (b) (4)	04 Feb 2021 17:22:26

US3522082

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:00:15

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered 'No (N)'	Yaman Ahmed (b) (4) (b) (4)	04 Feb 2021 17:22:26

US3522082

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:00:15

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered '3 Feb 2021'	Yaman Ahmed (b) (4) (b) (4)	04 Feb 2021 17:22:26

US3522082

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:00:15

Start time *(00:00-23:59)*

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	04 Feb 2021 17:22:26

US3522082

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:00:15

AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	04 Feb 2021 17:22:26

US3522082

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:00:15

Ongoing?

Audit	User	Time (GMT)
Signature has been broken.	Yaman Ahmed (b) (4) (b) (4)	06 Apr 2021 14:45:03
User entered 'No (N)' reason for change: New Information	Yaman Ahmed (b) (4) (b) (4)	06 Apr 2021 14:45:03
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered 'Yes (Y)'	Yaman Ahmed (b) (4) (b) (4)	04 Feb 2021 17:22:26

FDA-CBER-2022-1614-0812930

US3522082

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:00:15

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

Audit	User	Time (GMT)
Signature has been broken.	Yaman Ahmed (b) (4) (b) (4)	06 Apr 2021 14:45:03
User entered '4 Feb 2021' reason for change: Data Entry Error	Yaman Ahmed (b) (4) (b) (4)	06 Apr 2021 14:45:03
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	04 Feb 2021 17:22:26

FDA-CBER-2022-1614-0812931

US3522082

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:00:15

End time *(00:00-23:59)*

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	04 Feb 2021 17:22:26

US3522082

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:00:15

AE End Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	04 Feb 2021 17:22:26

US3522082

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:00:15

Severity

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Yaman Ahmed (b) (4) (b) (4)	04 Feb 2021 17:22:26

US3522082

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:00:15

Is the adverse event serious?

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
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	04 Feb 2021 17:22:48
User entered 'No (N)' reason for change: Data Entry Error	Yaman Ahmed (b) (4) (b) (4)	04 Feb 2021 17:22:48
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	04 Feb 2021 17:22:26
User entered 'Yes (Y)'	Yaman Ahmed (b) (4) (b) (4)	04 Feb 2021 17:22:26

US3522082

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:00:15

Death

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered '0'	Yaman Ahmed (b) (4) (b) (4)	04 Feb 2021 17:22:26

US3522082

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:00:15

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered '0'	Yaman Ahmed (b) (4) (b) (4)	04 Feb 2021 17:22:26

US3522082

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:00:15

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered '0'	Yaman Ahmed (b) (4) (b) (4)	04 Feb 2021 17:22:26

US3522082

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:00:15

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	04 Feb 2021 17:22:26

US3522082

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:00:15

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	04 Feb 2021 17:22:26

US3522082

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:00:15

Admitted to ICU?

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	04 Feb 2021 17:22:26

US3522082

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:00:15

Number of Days in ICU

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	04 Feb 2021 17:22:26

US3522082

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:00:15

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered '0'	Yaman Ahmed (b) (4) (b) (4)	04 Feb 2021 17:22:26

US3522082

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:00:15

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered '0'	Yaman Ahmed (b) (4) (b) (4)	04 Feb 2021 17:22:26

US3522082

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:00:15

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered '0'	Yaman Ahmed (b) (4) (b) (4)	04 Feb 2021 17:22:26

US3522082

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:00:15

Relationship to investigational product

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered 'Not Related (NOT RELATED)'	Yaman Ahmed (b) (4) (b) (4)	04 Feb 2021 17:22:26

US3522082

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:00:15

Relationship to Study Procedure

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered 'Not Related (NOT RELATED)'	Yaman Ahmed (b) (4) (b) (4)	04 Feb 2021 17:22:26

US3522082

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:00:15

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered 'Not Applicable (NOT APPLICABLE)'	Yaman Ahmed (b) (4) (b) (4)	04 Feb 2021 17:22:26

US3522082

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:00:15

None

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered '1'	Yaman Ahmed (b) (4) (b) (4)	04 Feb 2021 17:22:26

US3522082

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:00:15

Concomitant Medication

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered '0'	Yaman Ahmed (b) (4) (b) (4)	04 Feb 2021 17:22:26

US3522082

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:00:15

Concomitant Procedure

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered '0'	Yaman Ahmed (b) (4) (b) (4)	04 Feb 2021 17:22:26

US3522082

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:00:15

Outcome

Audit	User	Time (GMT)
Signature has been broken.	Yaman Ahmed (b) (4) (b) (4)	06 Apr 2021 14:45:03
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Yaman Ahmed (b) (4) (b) (4)	06 Apr 2021 14:45:03
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Yaman Ahmed (b) (4) (b) (4)	04 Feb 2021 17:22:26

US3522082

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:00:15

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

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	04 Feb 2021 17:22:26

US3522082

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:00:15

Narrative

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered 'HAS AN ICD IMPLANT WITH A MONITOR AND CARDIOLOGIST CALLED HIM YESTERDAY TO INFORM HIM THAT HIS HEART BEAT WAS NOT NORMAL (SKIPPING); HE ALSO TOLD HER THAT HE HAD CHEST PAIN LAST NIGHT SO SHE URGED HIM TO CONTACT HIS PCP WHO ADVISED HIM TO GO TO VA ER TODAY. HE IS ON HIS WAY RIGHT NOW (12:12 ON 04 FEB 2021) Update on 10 Feb 2021: states that at VA ER visit on 04 Feb 2021, bloodwork was ok, but they scheduled him for a nuclear stress test which, he's doing today, 10 Feb 2021 (has been there since morning and has 15 minutes left). Also, his cardiologist ordered a monitor patch for ICD for which he will use for two days (he is still waiting for it to come through the mail). Chest pain resolved on 04 Feb 2021 and he feels ok.' reason for change: New Information	Yaman Ahmed (b) (4) (b) (4)	10 Feb 2021 16:59:45
User entered 'Has an ICD implant with a monitor and cardiologist called him yesterday to inform him that his heart beat was not normal (skipping); he also told her that he had chest pain last night so she urged him to contact his PCP who advised him to go to VA ER today. He is on his way right now (12:12 on 04 Feb 2021)'	Yaman Ahmed (b) (4) (b) (4)	04 Feb 2021 17:22:26

US3522082

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:00:15

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '0'	System	04 Feb 2021 17:22:48
User entered '1'	System	04 Feb 2021 17:22:26

US3522082

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:00:15

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	04 Feb 2021 17:22:26

US3522082

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:00:15

Adverse event

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User closed query 'Per DM CLR RQ: Thanks for the response. Please update Concomitant medication eCRF with corresponding ConMed, if applicable or else clarify. ' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 10:45:54
Query 'Per DM CLR RQ: Thanks for the response. Please update Concomitant medication eCRF with corresponding ConMed, if applicable or else clarify. ' answered with 'chest pain resolved without medication' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 14:47:52
User opened query 'Per DM CLR RQ: Thanks for the response. Please update Concomitant medication eCRF with corresponding ConMed, if applicable or else clarify. ' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 10:24:18
User closed query 'Per DM CLR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if Chest Pain is respiratory related, musculoskeletal and connective tissue related , or general pain and discomfort. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 10:24:18
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Angina pectoris, LLT: Chest pain - cardiac - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Feb 2021 13:09:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Feb 2021 13:09:57
Data point term sent to Coder	System	22 Feb 2021 13:09:45
Query 'Per DM CLR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if Chest Pain is respiratory related, musculoskeletal and connective tissue related , or general pain and discomfort. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' answered with 'updated per narrative ' (Site from DM).	Alandra White (b) (4) (b) (4)	22 Feb 2021 13:09:44

US3522082

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:00:15

Adverse event

Audit	User	Time (GMT)
Coding entries removed.	Alandra White (b) (4) (b) (4)	22 Feb 2021 13:09:18
User entered 'Cardiac CHEST PAIN' reason for change: Data Entry Error	Alandra White (b) (4) (b) (4)	22 Feb 2021 13:09:18
User opened query 'Per DM CLR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if Chest Pain is respiratory related, musculoskeletal and connective tissue related , or general pain and discomfort. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 23:45:03
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Chest pain, LLT: Chest pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Feb 2021 17:25:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Feb 2021 17:25:48
Data point term sent to Coder	System	04 Feb 2021 17:24:29
User entered 'Chest pain'	Yaman Ahmed (b) (4) (b) (4)	04 Feb 2021 17:23:50

US3522082

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:00:15

Was this a medically-attended AE?

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered 'Yes (Y)'	Yaman Ahmed (b) (4) (b) (4)	04 Feb 2021 17:23:50

US3522082

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:00:15

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered 'No (N)'	Yaman Ahmed (b) (4) (b) (4)	04 Feb 2021 17:23:50

US3522082

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:00:15

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered 'No (N)'	Yaman Ahmed (b) (4) (b) (4)	04 Feb 2021 17:23:50

US3522082

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:00:15

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered '3 Feb 2021'	Yaman Ahmed (b) (4) (b) (4)	04 Feb 2021 17:23:50

US3522082

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:00:15

Start time *(00:00-23:59)*

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	04 Feb 2021 17:23:50

US3522082

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:00:15

AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	04 Feb 2021 17:23:50

US3522082

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:00:15

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered 'No (N)' reason for change: New Information	Yaman Ahmed (b) (4) (b) (4)	10 Feb 2021 17:01:10
User entered 'Yes (Y)'	Yaman Ahmed (b) (4) (b) (4)	04 Feb 2021 17:23:50

US3522082

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:00:15

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

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered '4 Feb 2021' reason for change: New Information	Yaman Ahmed (b) (4) (b) (4)	10 Feb 2021 17:01:10
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	04 Feb 2021 17:23:50

US3522082

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:00:15

End time *(00:00-23:59)*

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	04 Feb 2021 17:23:50

US3522082

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:00:15

AE End Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	04 Feb 2021 17:23:50

US3522082

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:00:15

Severity

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Yaman Ahmed (b) (4) (b) (4)	04 Feb 2021 17:23:50

Is the adverse event serious?

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered 'No (N)'	Yaman Ahmed (b) (4) (b) (4)	04 Feb 2021 17:23:50

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:00:15

Death

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered '0'	Yaman Ahmed (b) (4) (b) (4)	04 Feb 2021 17:23:50

US3522082

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:00:15

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered '0'	Yaman Ahmed (b) (4) (b) (4)	04 Feb 2021 17:23:50

US3522082

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:00:15

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered '0'	Yaman Ahmed (b) (4) (b) (4)	04 Feb 2021 17:23:50

US3522082

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:00:15

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	04 Feb 2021 17:23:50

US3522082

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:00:15

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	04 Feb 2021 17:23:50

US3522082

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:00:15

Admitted to ICU?

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	04 Feb 2021 17:23:50

US3522082

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:00:15

Number of Days in ICU

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	04 Feb 2021 17:23:50

US3522082

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:00:15

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered '0'	Yaman Ahmed (b) (4) (b) (4)	04 Feb 2021 17:23:50

US3522082

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:00:15

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered '0'	Yaman Ahmed (b) (4) (b) (4)	04 Feb 2021 17:23:50

US3522082

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:00:15

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered '0'	Yaman Ahmed (b) (4) (b) (4)	04 Feb 2021 17:23:50

US3522082

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:00:15

Relationship to investigational product

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered 'Not Related (NOT RELATED)'	Yaman Ahmed (b) (4) (b) (4)	04 Feb 2021 17:23:50

US3522082

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:00:15

Relationship to Study Procedure

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered 'Not Related (NOT RELATED)'	Yaman Ahmed (b) (4) (b) (4)	04 Feb 2021 17:23:50

US3522082

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:00:15

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered 'Not Applicable (NOT APPLICABLE)'	Yaman Ahmed (b) (4) (b) (4)	04 Feb 2021 17:23:50

US3522082

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:00:15

None

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered '1'	Yaman Ahmed (b) (4) (b) (4)	04 Feb 2021 17:23:50

US3522082

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:00:15

Concomitant Medication

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered '0'	Yaman Ahmed (b) (4) (b) (4)	04 Feb 2021 17:23:50

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:00:15

Concomitant Procedure

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered '0'	Yaman Ahmed (b) (4) (b) (4)	04 Feb 2021 17:23:50

US3522082

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:00:15

Outcome

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Yaman Ahmed (b) (4) (b) (4)	10 Feb 2021 17:01:10
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Yaman Ahmed (b) (4) (b) (4)	04 Feb 2021 17:23:50

US3522082

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:00:15

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

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	04 Feb 2021 17:23:50

US3522082

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:00:15

Narrative

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Narrative = MONITOR PATCH FOR ICD. Please review and verify if this was already performed. If yes, ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 00:35:48
User opened query 'Per DM CLR: Narrative = 04 FEB 2021, BLOODWORK. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 00:34:56
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User closed query 'Per DM CLR: Narrative = HAS AN ICD IMPLANT WITH A MONITOR. However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 11:20:06
Query 'Per DM CLR: Narrative = HAS AN ICD IMPLANT WITH A MONITOR. However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate.' answered with 'updated MH' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 14:48:49
User opened query 'Per DM CLR: Narrative = HAS AN ICD IMPLANT WITH A MONITOR. However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 23:44:57

FDA-CBER-2022-1614-0812989

Audit	User	Time (GMT)
User entered 'HAS AN ICD IMPLANT WITH A MONITOR AND CARDIOLOGIST CALLED HIM YESTERDAY TO INFORM HIM THAT HIS HEART BEAT WAS NOT NORMAL (SKIPPING); HE ALSO TOLD HER THAT HE HAD CHEST PAIN LAST NIGHT SO SHE URGED HIM TO CONTACT HIS PCP WHO ADVISED HIM TO GO TO VA ER TODAY. HE IS ON HIS WAY RIGHT NOW (12:12 ON 04 FEB 2021) Update on 10 Feb 2021: states that at VA ER visit on 04 Feb 2021, bloodwork was ok, but they scheduled him for a nuclear stress test which, he's doing today, 10 Feb 2021 (has been there since morning and has 15 minutes left). Also, his cardiologist ordered a monitor patch for ICD for which he will use for two days (he is still waiting for it to come through the mail). Chest pain resolved on 04 Feb 2021 and he feels ok.' reason for change: New Information	Yaman Ahmed (b) (4) (b) (4)	10 Feb 2021 17:00:35
User entered 'Has an ICD implant with a monitor and cardiologist called him yesterday to inform him that his heart beat was not normal (skipping); he also told her that he had chest pain last night so she urged him to contact his PCP who advised him to go to VA ER today. He is on his way right now (12:12 on 04 Feb 2021)'	Yaman Ahmed (b) (4) (b) (4)	04 Feb 2021 17:23:50

US3522082
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 08:00:15
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '0'	System	04 Feb 2021 17:23:50

US3522082

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:00:15

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	04 Feb 2021 17:23:50

US3522082

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:00:15

AEID

Audit	User	Time (GMT)
User closed query 'CRA is unable to review this event in any source. Please kindly provide details of the XRAY (and result) for CRA review.' (Site from CRA).	(b) (4), (b) (6)	30 Apr 2021 19:37:51
Query 'CRA is unable to review this event in any source. Please kindly provide details of the XRAY (and result) for CRA review.' answered with 'as of 30 apr 2021 we have yet to receive the documents back after sending the request for medical records to the VA ' (Site from CRA).	Sharon Mathys (b) (4) (b) (4)	30 Apr 2021 11:45:26
User opened query 'CRA is unable to review this event in any source. Please kindly provide details of the XRAY (and result) for CRA review.' (Site from CRA).	(b) (4), (b) (6)	30 Apr 2021 11:36:47
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:13:44
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:38:59
User entered 'USA-US131-2021-mRNA-1273-P301000010'	System	05 Mar 2021 15:38:47
User entered 'New'	(b) (4), (b) (6)	05 Mar 2021 15:38:47

US3522082

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:00:15

Adverse event

Audit	User	Time (GMT)
User opened query 'Per MM: The AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate). ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 12:30:13
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Respiratory tract disorders NEC, PT: Respiratory tract congestion, LLT: Respiratory tract congestion - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Mar 2021 17:26:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Mar 2021 17:26:02
Data point term sent to Coder	System	04 Mar 2021 17:24:34
User entered 'chest congestion'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:24:01

US3522082

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:00:15

Was this a medically-attended AE?

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered 'Yes (Y)'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:24:01

US3522082

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:00:15

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered 'No (N)'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:24:01

US3522082

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:00:15

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
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)	11 Mar 2021 14:07:28
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered 'No (N)'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:24:01

US3522082

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:00:15

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered '1 Mar 2021'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:24:01

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:24:01

FDA-CBER-2022-1614-0812999

US3522082

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:00:15

AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	04 Mar 2021 17:24:01

US3522082

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:00:15

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered 'Yes (Y)'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:24:01

US3522082

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:00:15

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

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	11 Mar 2021 14:07:52
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:24:01

US3522082

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:00:15

End time *(00:00-23:59)*

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:24:01

US3522082
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 08:00:15

AE End Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	04 Mar 2021 17:24:01

US3522082
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 08:00:15

Severity

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:24:01

US3522082

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:00:15

Is the adverse event serious?

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User closed query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	04 Mar 2021 17:24:23
User entered 'Yes (Y)' reason for change: Data Entry Error	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:24:23
User opened query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	04 Mar 2021 17:24:01
User entered 'No (N)'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:24:01

Death

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered '0'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:24:01

FDA-CBER-2022-1614-0813007

US3522082

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:00:15

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered '0'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:24:01

US3522082

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:00:15

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered '1'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:24:01

US3522082

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:00:15

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered '1 Mar 2021'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:24:01

US3522082

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:00:15

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so' (Site from Safety).	(b) (4), (b) (6)	11 Mar 2021 14:09:41
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered '2 Mar 2021'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:24:01

US3522082
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 08:00:15
Admitted to ICU?

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered 'No (N)'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:24:01

US3522082

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:00:15

Number of Days in ICU

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:24:01

US3522082

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:00:15

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered '0'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:24:01

US3522082

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:00:15

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered '0'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:24:01

US3522082

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:00:15

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered '0'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:24:01

US3522082
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 08:00:15
Relationship to investigational product

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered 'Not Related (NOT RELATED)'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:24:01

US3522082

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:00:15

Relationship to Study Procedure

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered 'Not Related (NOT RELATED)'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:24:01

US3522082

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:00:15

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered 'Not Applicable (NOT APPLICABLE)'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:24:01

US3522082

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:00:15

None

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered '0'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:24:01

US3522082

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:00:15

Concomitant Medication

Audit	User	Time (GMT)
User opened query 'PV Query - Please provide start dates (if available) for concomitant medications pantoprazole, carvedilol, daily multivitamin, acetylsalicylic acid, furosemide, lisinopril, ferrous sulfate, apixaban, and atorvastatin and confirm if in use at the onset of the event. Please update this information in the EDC.' (Site from Safety).	(b) (4), (b) (6)	11 Mar 2021 14:08:54
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered '1'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:24:01

US3522082

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:00:15

Concomitant Procedure

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide results of echocardiogram of 24 Mar 2021 when available.' (Site from Safety).	(b) (4), (b) (6)	11 Mar 2021 14:10:02
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)	11 Mar 2021 14:08:19
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered '1'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:24:01

US3522082

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:00:15

Outcome

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	11 Mar 2021 14:08:36
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:24:01

US3522082

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:00:15

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

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:24:01

US3522082
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 08:00:15
Narrative

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Narrative indicates that the subject was prescribed with Sacubitril. However, there is no recorded ConMed that match the information. Please review and update to record the corresponding ConMed as applicable. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 12:43:16
Query 'Per DM CLR: Narrative indicates that the subject was prescribed with Sacubitril. However, there is no recorded ConMed that match the information. Please review and update to record the corresponding ConMed as applicable. Otherwise, clarify.' answered with 'updated' (Site from DM).	Yaman Ahmed (b) (4) (b) (4)	06 Apr 2021 15:45:52
User opened query 'Per DM CLR: Narrative indicates that the subject was prescribed with Sacubitril. However, there is no recorded ConMed that match the information. Please review and update to record the corresponding ConMed as applicable. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 19:56:15
Signature has been broken.	Yaman Ahmed (b) (4) (b) (4)	16 Mar 2021 19:53:18
User entered 'HE SAID HE HAS BEEN DOING WELL BUT WENT FOR A FOLLOW UP ON 01 MAR 2021 AND THEY DID AN X-RAY OF HIS CHEST AND SAW CHEST CONGESTION SO THEY HAD HIM STAY OVERNIGHT FOR OBSERVATION AND HE WAS SWITCHED FROM LISINOPRIL 40 MG ONCE DAILY TO EMPAGLIFLOZIN (JARIDANCE) 10 MG ONCE DAILY FOR THE CHEST CONGESTION. HE WAS ALSO PRESCRIBED SACUBITRIL-valsartan24/26 MG TWICE DAILY, WHICH HE WILL START 05 MAR 2021. HE IS SCHEDULED FOR AN ECHO ON 24 MAR 2021' reason for change: Data Entry Error	Yaman Ahmed (b) (4) (b) (4)	16 Mar 2021 19:53:18
User opened query 'PV Query - Can the start dates for the medical history of coronary artery disease, implantable defibrillator user, hypertension, iron deficiency anemia, and gastroesophageal reflux disease be provided? If yes, please update in EDC.' (Site from Safety).	(b) (4), (b) (6)	11 Mar 2021 14:09:13
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01

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US3522082

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:00:15

Narrative

Audit	User		Time (GMT)
User entered 'he said he has been doing well but went for a follow up on 01 Mar 2021 and they did an x-ray of his chest and saw chest congestion so they had him stay overnight for observation and he was switched from Lisinopril 40 mg once daily to Empagliflozin (Jaridance) 10 mg once daily for the chest congestion. He was also prescribed Sacubitril 26 mg twice daily, which he will start 05 Mar 2021. He is scheduled for an ECHO on 24 Mar 2021'	Yaman Ahmed	(b) (4) (b) (4)	04 Mar 2021 17:24:01

US3522082

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:00:15

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '1'	System	04 Mar 2021 17:24:23
User entered '0'	System	04 Mar 2021 17:24:01

US3522082

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:00:15

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	04 Mar 2021 17:24:01

US3522082

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:00:15

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	04 Mar 2021 17:24:01

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 08:00:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:48:01
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:51:50
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	13 Aug 2020 18:06:41

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:00:15

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:52:05
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: CARVEDILOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 22:14:17
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 22:14:17
Data point term sent to Coder	System	13 Aug 2020 18:07:42
User entered 'Carvedilol'	Sharon Mathys (b) (4) (b) (4)	13 Aug 2020 18:07:31

FDA-CBER-2022-1614-0813031

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:00:15

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:52:05
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	13 Aug 2020 18:07:31

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:00:15

Indication

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:52:05
User entered 'CAD'	Sharon Mathys (b) (4) (b) (4)	13 Aug 2020 18:07:31

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:00:15

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
DataPoint Un-verified.	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:12:25
Signature has been broken.	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:12:25
User entered '25' reason for change: New Information	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:12:25
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:52:05
User entered 'UNKN'	Sharon Mathys (b) (4) (b) (4)	13 Aug 2020 18:07:31

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:00:15

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
DataPoint Un-verified.	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:12:25
Signature has been broken.	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:12:25
User entered 'mg (mg)' reason for change: New Information	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:12:25
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:52:05
User entered 'Other (OTHER)'	Sharon Mathys (b) (4) (b) (4)	13 Aug 2020 18:07:31

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:00:15

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
DataPoint Un-verified.	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:12:25
Signature has been broken.	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:12:25
User entered empty; reason for change New Information	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:12:25
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:52:05
User entered 'UNKN'	Sharon Mathys (b) (4) (b) (4)	13 Aug 2020 18:07:31

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:00:15

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:52:05
User entered 'twice daily (BID)'	Sharon Mathys (b) (4) (b) (4)	13 Aug 2020 18:07:31

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:00:15

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:52:05
User entered empty.	Sharon Mathys (b) (4) (b) (4)	13 Aug 2020 18:07:31

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:00:15

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:52:05
User entered 'Oral (ORAL)'	Sharon Mathys (b) (4) (b) (4)	13 Aug 2020 18:07:31

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:00:15

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:52:05
User entered empty.	Sharon Mathys (b) (4) (b) (4)	13 Aug 2020 18:07:31

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:00:15

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:52:05
User entered empty.	Sharon Mathys (b) (4) (b) (4)	13 Aug 2020 18:07:31

FDA-CBER-2022-1614-0813041

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:00:15

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:52:05
User entered '1'	Sharon Mathys (b) (4) (b) (4)	13 Aug 2020 18:07:31

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:00:15

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:52:05
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	13 Aug 2020 18:07:31

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:00:15

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

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:52:05
User entered empty.	Sharon Mathys (b) (4) (b) (4)	13 Aug 2020 18:07:31

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:00:15

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:52:05
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	13 Aug 2020 18:07:31

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:00:15

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '2'	System	13 Aug 2020 18:07:31

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:00:15

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 18:07:31

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:00:15

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Aug 2020 18:07:31

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:00:15

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:52:07
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 18:09:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 18:09:25
Data point term sent to Coder	System	13 Aug 2020 18:08:43
User entered 'Aspirin'	Sharon Mathys (b) (4) (b) (4)	13 Aug 2020 18:08:15

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:00:15

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:52:07
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	13 Aug 2020 18:08:15

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:00:15

Indication

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:52:07
User entered 'CAD'	Sharon Mathys (b) (4) (b) (4)	13 Aug 2020 18:08:15

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:00:15

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:52:07
User entered '81'	Sharon Mathys (b) (4) (b) (4)	13 Aug 2020 18:08:15

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:00:15

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:52:07
User entered 'mg (mg)'	Sharon Mathys (b) (4) (b) (4)	13 Aug 2020 18:08:15

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:00:15

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:52:07
User entered empty.	Sharon Mathys (b) (4) (b) (4)	13 Aug 2020 18:08:15

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:00:15

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:52:07
User entered 'once daily (QD)'	Sharon Mathys (b) (4) (b) (4)	13 Aug 2020 18:08:15

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:00:15

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:52:07
User entered empty.	Sharon Mathys (b) (4) (b) (4)	13 Aug 2020 18:08:15

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:00:15

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:52:07
User entered 'Oral (ORAL)'	Sharon Mathys (b) (4) (b) (4)	13 Aug 2020 18:08:15

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:00:15

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:52:07
User entered empty.	Sharon Mathys (b) (4) (b) (4)	13 Aug 2020 18:08:15

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:00:15

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:52:07
User entered empty.	Sharon Mathys (b) (4) (b) (4)	13 Aug 2020 18:08:15

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:00:15

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:52:07
User entered '1'	Sharon Mathys (b) (4) (b) (4)	13 Aug 2020 18:08:15

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:00:15

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:52:07
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	13 Aug 2020 18:08:15

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:00:15

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

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:52:07
User entered empty.	Sharon Mathys (b) (4) (b) (4)	13 Aug 2020 18:08:15

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:00:15

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:52:07
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	13 Aug 2020 18:08:15

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:00:15

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 18:08:15

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:00:15

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 18:08:15

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:00:15

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Aug 2020 18:08:15

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:00:15

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:52:09
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE, PRODUCTSYNONYM: LASIX [FUROSEMIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 07:11:14
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 07:11:14
Data point term sent to Coder	System	13 Aug 2020 18:09:44
User entered 'Lasix'	Sharon Mathys (b) (4) (b) (4)	13 Aug 2020 18:08:57

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:00:15

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:52:09
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	13 Aug 2020 18:08:57

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:00:15

Indication

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:52:09
User entered 'CAD'	Sharon Mathys (b) (4) (b) (4)	13 Aug 2020 18:08:57

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:00:15

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
DataPoint Un-verified.	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:13:12
Signature has been broken.	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:13:12
User entered '40' reason for change: New Information	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:13:12
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:52:09
User entered 'UNKN'	Sharon Mathys (b) (4) (b) (4)	13 Aug 2020 18:08:57

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:00:15

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
DataPoint Un-verified.	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:13:12
Signature has been broken.	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:13:12
User entered 'mg (mg)' reason for change: New Information	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:13:12
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:52:09
User entered 'Other (OTHER)'	Sharon Mathys (b) (4) (b) (4)	13 Aug 2020 18:08:57

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:00:15

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
DataPoint Un-verified.	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:13:12
Signature has been broken.	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:13:12
User entered empty; reason for change New Information	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:13:12
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:52:09
User entered 'UNKN'	Sharon Mathys (b) (4) (b) (4)	13 Aug 2020 18:08:57

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:00:15

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:52:09
User entered 'once daily (QD)'	Sharon Mathys (b) (4) (b) (4)	13 Aug 2020 18:08:57

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:00:15

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:52:09
User entered empty.	Sharon Mathys (b) (4) (b) (4)	13 Aug 2020 18:08:57

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:00:15

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:52:09
User entered 'Oral (ORAL)'	Sharon Mathys (b) (4) (b) (4)	13 Aug 2020 18:08:57

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:00:15

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:52:09
User entered empty.	Sharon Mathys (b) (4) (b) (4)	13 Aug 2020 18:08:57

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:00:15

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:52:09
User entered empty.	Sharon Mathys (b) (4) (b) (4)	13 Aug 2020 18:08:57

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:00:15

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:52:09
User entered '1'	Sharon Mathys (b) (4) (b) (4)	13 Aug 2020 18:08:57

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:00:15

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:52:09
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	13 Aug 2020 18:08:57

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:00:15

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

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:52:09
User entered empty.	Sharon Mathys (b) (4) (b) (4)	13 Aug 2020 18:08:57

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:00:15

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:52:09
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	13 Aug 2020 18:08:57

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:00:15

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 18:08:57

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:00:15

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 18:08:57

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:00:15

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Aug 2020 18:08:57

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:00:15

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:52:11
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: RIVAROXABAN, PRODUCTSYNONYM: XARELTO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 18:11:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 18:11:21
Data point term sent to Coder	System	13 Aug 2020 18:10:47
User entered 'xarelto'	Sharon Mathys (b) (4) (b) (4)	13 Aug 2020 18:09:53

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:00:15

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:52:11
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	13 Aug 2020 18:09:53

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:00:15

Indication

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:52:11
User entered 'CAD'	Sharon Mathys (b) (4) (b) (4)	13 Aug 2020 18:09:53

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:00:15

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 18:01:29
User closed query 'Per CDM: Per CCG's Dose per administration should be "UNK" if data is not available.' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 03:20:13
Query 'Per CDM: Per CCG's Dose per administration should be "UNK" if data is not available.' answered with 'changed to UNK' (Site from DM).	Marcus Zervos (b) (4) (b) (4)	12 Mar 2021 15:28:55
DataPoint Un-verified.	Marcus Zervos (b) (4) (b) (4)	12 Mar 2021 15:28:37
Signature has been broken.	Marcus Zervos (b) (4) (b) (4)	12 Mar 2021 15:28:37
User entered 'UNK' reason for change: Data Entry Error	Marcus Zervos (b) (4) (b) (4)	12 Mar 2021 15:28:37
User opened query 'Per CDM: Per CCG's Dose per administration should be "UNK" if data is not available.' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 12:57:39
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:52:11
User entered 'UNKN'	Sharon Mathys (b) (4) (b) (4)	13 Aug 2020 18:09:53

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:00:15

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:52:11
User entered 'Other (OTHER)'	Sharon Mathys (b) (4) (b) (4)	13 Aug 2020 18:09:53

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:00:15

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:52:11
User entered 'UNKN'	Sharon Mathys (b) (4) (b) (4)	13 Aug 2020 18:09:53

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:00:15

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:52:11
User entered 'unknown (UNKNOWN)'	Sharon Mathys (b) (4) (b) (4)	13 Aug 2020 18:09:53

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:00:15

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:52:11
User entered empty.	Sharon Mathys (b) (4) (b) (4)	13 Aug 2020 18:09:53

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:00:15

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:52:11
User entered 'Oral (ORAL)'	Sharon Mathys (b) (4) (b) (4)	13 Aug 2020 18:09:53

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:00:15

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:52:11
User entered empty.	Sharon Mathys (b) (4) (b) (4)	13 Aug 2020 18:09:53

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US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:00:15

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:52:11
User entered empty.	Sharon Mathys (b) (4) (b) (4)	13 Aug 2020 18:09:53

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:00:15

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:52:11
User entered '1'	Sharon Mathys (b) (4) (b) (4)	13 Aug 2020 18:09:53

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:00:15

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
DataPoint Un-verified.	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:14:00
Signature has been broken.	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:14:00
User entered 'No (N)' reason for change: New Information	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:14:00
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:52:11
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	13 Aug 2020 18:09:53

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:00:15

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

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
DataPoint Un-verified.	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:14:00
Signature has been broken.	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:14:00
User entered 'UN Dec 2020' reason for change: Data Entry Error	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:14:00
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	21 Feb 2021 21:20:17
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:52:11
User entered empty.	Sharon Mathys (b) (4) (b) (4)	13 Aug 2020 18:09:53

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:00:15

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	21 Feb 2021 21:20:17
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 13:52:11
User entered 'No (N)'	Sharon Mathys (b) (4)	13 Aug 2020 18:09:53
	(b) (4)	

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:00:15

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 18:09:53

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:00:15

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 18:09:53

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:00:15

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 18:09:53

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:00:15

Name of Medication

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, consider recording an AE of Worsening CAD during this timeframe; update Con Med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 15:04:58
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, consider recording an AE of Worsening CAD during this timeframe; update Con Med indication or provide clarification. ' answered with 'it was not due to worsening but preference of Apixaban over Xarelto according to participant ' (Site from DM).	Yaman Ahmed (b) (4) (b) (4)	06 Apr 2021 15:55:36
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, consider recording an AE of Worsening CAD during this timeframe; update Con Med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 06:19:23
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Mar 2021 17:17:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Mar 2021 17:17:01
Data point term sent to Coder	System	04 Mar 2021 17:16:17
User entered 'apixaban'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:15:30

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:00:15

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered 'No (N)'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:15:30

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:00:15

Indication

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered 'CAD'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:15:30

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:00:15

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered '2.5'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:15:30

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:00:15

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered 'mg (mg)'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:15:30

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:00:15

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:15:30

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:00:15

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered 'twice daily (BID)'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:15:30

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:00:15

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:15:30

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:00:15

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered 'Oral (ORAL)'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:15:30

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:00:15

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:15:30

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:00:15

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered 'UN Dec 2020'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:15:30

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:00:15

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered '0'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:15:30

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:00:15

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Mar 2021 17:15:37
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Mar 2021 17:15:37
User entered 'Yes (Y)' reason for change: Data Entry Error	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:15:37
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Mar 2021 17:15:30
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:15:30

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:00:15

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

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:15:30

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:00:15

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Mar 2021 17:15:37
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Mar 2021 17:15:37
User entered 'No (N)' reason for change: Data Entry Error	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:15:37
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Mar 2021 17:15:30
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:15:30

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:00:15

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '2'	System	04 Mar 2021 17:15:30

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:00:15

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	04 Mar 2021 17:15:30

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:00:15

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Mar 2021 17:15:30

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:00:15

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
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)	04 Mar 2021 17:18:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Mar 2021 17:18:02
Data point term sent to Coder	System	04 Mar 2021 17:17:18
User entered 'Lisinopril'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:16:40

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:00:15

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered 'No (N)'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:16:40

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:00:15

Indication

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered 'hypertension'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:16:40

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:00:15

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered '40'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:16:40

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:00:15

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered 'mg (mg)'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:16:40

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:00:15

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:16:40

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:00:15

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered 'once daily (QD)'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:16:40

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:00:15

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:16:40

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:00:15

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered 'Oral (ORAL)'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:16:40

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:00:15

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:16:40

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:00:15

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:16:40

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:00:15

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered '1'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:16:40

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:00:15

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered 'No (N)'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:16:40

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:00:15

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

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered '1 Mar 2021'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:16:40

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:00:15

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered 'No (N)'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:16:40

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:00:15

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	04 Mar 2021 17:16:40

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:00:15

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	04 Mar 2021 17:16:40

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:00:15

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Mar 2021 17:16:40

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:00:15

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: SODIUM-GLUCOSE CO-TRANSPORTER 2 (SGLT2) INHIBITORS, PRODUCT: EMPAGLIFLOZIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Mar 2021 20:33:17
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Mar 2021 20:33:17
Data point term sent to Coder	System	04 Mar 2021 17:17:18
User entered 'empagliflozin'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:17:12

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:00:15

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered 'No (N)'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:17:12

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:00:15

Indication

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered 'CAD'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:17:12

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:00:15

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered '10'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:17:12

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:00:15

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered 'mg (mg)'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:17:12

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:00:15

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:17:12

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:00:15

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered 'once daily (QD)'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:17:12

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:00:15

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:17:12

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:00:15

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered 'Oral (ORAL)'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:17:12

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:00:15

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:17:12

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:00:15

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered '1 Mar 2021'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:17:12

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:00:15

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered '0'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:17:12

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:00:15

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered 'Yes (Y)'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:17:12

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:00:15

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

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:17:12

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:00:15

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered 'No (N)'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:17:12

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:00:15

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	04 Mar 2021 17:17:12

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:00:15

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	04 Mar 2021 17:17:12

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:00:15

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Mar 2021 17:17:12

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:00:15

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: IRON PREPARATIONS, ATC: IRON BIVALENT, ORAL PREPARATIONS, PRODUCT: FERROUS SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Mar 2021 17:19:05
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Mar 2021 17:19:05
Data point term sent to Coder	System	04 Mar 2021 17:18:19
User entered 'ferrous sulfate'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:18:10

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:00:15

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered 'No (N)'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:18:10

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:00:15

Indication

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered 'iron deficiency anemia'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:18:10

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:00:15

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered '325'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:18:10

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:00:15

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered 'mg (mg)'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:18:10

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:00:15

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:18:10

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:00:15

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered 'once daily (QD)'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:18:10

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:00:15

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:18:10

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:00:15

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered 'Oral (ORAL)'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:18:10

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 08:00:15
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:18:10

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:00:15

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:18:10

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:00:15

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered '1'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:18:10

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:00:15

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered 'Yes (Y)'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:18:10

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:00:15

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

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:18:10

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:00:15

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered 'No (N)'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:18:10

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:00:15

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	04 Mar 2021 17:18:10

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:00:15

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	04 Mar 2021 17:18:10

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:00:15

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Mar 2021 17:18:10

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:00:15

Name of Medication

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, consider recording an AE of Worsening CAD during this timeframe; update Con Med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 13:42:01
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, consider recording an AE of Worsening CAD during this timeframe; update Con Med indication or provide clarification. ' answered with 'It was not a worsening, medication pre-dates study according to participant ' (Site from DM).	Yaman Ahmed (b) (4) (b) (4)	06 Apr 2021 15:57:28
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, consider recording an AE of Worsening CAD during this timeframe; update Con Med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 06:19:35
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Mar 2021 17:20:09
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Mar 2021 17:20:09
Data point term sent to Coder	System	04 Mar 2021 17:19:23
User entered 'atorvastatin'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:18:42

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:00:15

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered 'No (N)'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:18:42

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:00:15

Indication

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered 'CAD'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:18:42

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:00:15

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered '80'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:18:42

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:00:15

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered 'mg (mg)'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:18:42

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:00:15

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:18:42

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:00:15

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered 'once daily (QD)'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:18:42

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:00:15

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:18:42

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:00:15

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered 'Oral (ORAL)'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:18:42

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:00:15

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:18:42

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:00:15

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:18:42

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:00:15

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered '1'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:18:42

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:00:15

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered 'Yes (Y)'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:18:42

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:00:15

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

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:18:42

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:00:15

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered 'No (N)'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:18:42

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:00:15

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	04 Mar 2021 17:18:42

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:00:15

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	04 Mar 2021 17:18:42

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 08:00:15

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Mar 2021 17:18:42

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:00:15

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Mar 2021 17:20:10
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Mar 2021 17:20:10
Data point term sent to Coder	System	04 Mar 2021 17:19:23
User entered 'pantoprazole'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:19:16

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:00:15

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered 'No (N)'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:19:16

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:00:15

Indication

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered 'GERD'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:19:16

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:00:15

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered '20'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:19:16

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:00:15

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered 'mg (mg)'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:19:16

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:00:15

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:19:16

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:00:15

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered 'once daily (QD)'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:19:16

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:00:15

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:19:16

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:00:15

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered 'Oral (ORAL)'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:19:16

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:00:15

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:19:16

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:00:15

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:19:16

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:00:15

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered '1'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:19:16

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:00:15

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered 'Yes (Y)'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:19:16

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:00:15

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

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:19:16

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:00:15

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered 'No (N)'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:19:16

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:00:15

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	04 Mar 2021 17:19:16

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:00:15

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	04 Mar 2021 17:19:16

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 08:00:15

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Mar 2021 17:19:16

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:00:15

Name of Medication

Audit	User	Time (GMT)
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)	15 Mar 2021 02:19:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 02:19:48
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
Data point term sent to Coder	System	04 Mar 2021 17:22:31
User entered 'daily multivitamin'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:21:40

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:00:15

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered 'Yes (Y)'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:21:40

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:00:15

Indication

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered 'dietary supplement'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:21:40

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:00:15

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered 'unknown'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:21:40

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:00:15

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered 'Other (OTHER)'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:21:40

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:00:15

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered 'unknown'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:21:40

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:00:15

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered 'once daily (QD)'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:21:40

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:00:15

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:21:40

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:00:15

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered 'Oral (ORAL)'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:21:40

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:00:15

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:21:40

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:00:15

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:21:40

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:00:15

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered '1'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:21:40

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:00:15

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered 'Yes (Y)'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:21:40

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:00:15

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

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:21:40

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:00:15

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered 'No (N)'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:21:40

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:00:15

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	04 Mar 2021 17:21:40

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:00:15

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	04 Mar 2021 17:21:40

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 08:00:15

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Mar 2021 17:21:40

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:00:15

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	12 Apr 2021 11:52:25
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), COMBINATIONS, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), OTHER COMBINATIONS, PRODUCT: SACUBITRIL;VALSARTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 10:09:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 10:09:37
Data point term sent to Coder	System	06 Apr 2021 15:48:46
User entered 'sacubitril-Valsartan'	Yaman Ahmed (b) (4) (b) (4)	06 Apr 2021 15:48:19

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	12 Apr 2021 11:52:25
User entered 'No (N)'	Yaman Ahmed (b) (4) (b) (4)	06 Apr 2021 15:48:19

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:00:15

Indication

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	12 Apr 2021 11:52:25
User entered 'CAD'	Yaman Ahmed (b) (4) (b) (4)	06 Apr 2021 15:48:19

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:00:15

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	12 Apr 2021 11:52:25
User entered '24/26'	Yaman Ahmed (b) (4) (b) (4)	06 Apr 2021 15:48:19

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:00:15

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	12 Apr 2021 11:52:25
User entered 'mg (mg)'	Yaman Ahmed (b) (4) (b) (4)	06 Apr 2021 15:48:19

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:00:15

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	12 Apr 2021 11:52:25
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	06 Apr 2021 15:48:19

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:00:15

Frequency

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	12 Apr 2021 11:52:25
User entered 'twice daily (BID)'	Yaman Ahmed (b) (4) (b) (4)	06 Apr 2021 15:48:19

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:00:15

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	12 Apr 2021 11:52:25
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	06 Apr 2021 15:48:19

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:00:15

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	12 Apr 2021 11:52:25
User entered 'Oral (ORAL)'	Yaman Ahmed (b) (4) (b) (4)	06 Apr 2021 15:48:19

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:00:15

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	12 Apr 2021 11:52:25
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	06 Apr 2021 15:48:19

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:00:15

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	12 Apr 2021 11:52:25
User entered '5 Mar 2021'	Yaman Ahmed (b) (4) (b) (4)	06 Apr 2021 15:48:19

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:00:15

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	12 Apr 2021 11:52:25
User entered '0'	Yaman Ahmed (b) (4) (b) (4)	06 Apr 2021 15:48:19

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:00:15

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	12 Apr 2021 11:52:25
User entered 'Yes (Y)'	Yaman Ahmed (b) (4) (b) (4)	06 Apr 2021 15:48:19

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:00:15

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

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	12 Apr 2021 11:52:25
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	06 Apr 2021 15:48:19

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:00:15

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	12 Apr 2021 11:52:25
User entered 'No (N)'	Yaman Ahmed (b) (4) (b) (4)	06 Apr 2021 15:48:19

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:00:15

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '2'	System	06 Apr 2021 15:48:19

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:00:15

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	06 Apr 2021 15:48:19

US3522082

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 08:00:15

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Apr 2021 15:48:19

US3522082

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 08:00:15

Were any concomitant procedures performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:48:01
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:51:49
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered 'Yes (Y)'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:24:36

US3522082

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:00:15

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered '1 Mar 2021'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:25:00

US3522082

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:00:15

Procedure/Surgery

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered 'chest x-ray'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:25:00

US3522082

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:00:15

Indication

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered 'Adverse Event (AE)'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:25:00

US3522082

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:00:15

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:25:00

US3522082

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:00:15

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered '10 Feb 2021'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:26:08

US3522082

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:00:15

Procedure/Surgery

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered 'nuclear stress test'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:26:08

US3522082

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:00:15

Indication

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered 'Adverse Event (AE)'	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:26:08

US3522082

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:00:15

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:32:01
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	04 Mar 2021 17:26:08

US3522082

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:00:15

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 18:01:29
User entered '10 Mar 2021'	(b) (4), (b) (6)	16 Mar 2021 14:37:48

US3522082

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:00:15

Procedure/Surgery

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 18:01:29
User entered 'Bloodwork- lactate and aspartate aminotransferase'	(b) (4), (b) (6)	16 Mar 2021 14:37:48

US3522082

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:00:15

Indication

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 18:01:29
User entered 'Medical History (MH)'	(b) (4), (b) (6)	16 Mar 2021 14:37:48

US3522082

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:00:15

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 18:01:29
User entered empty.	(b) (4), (b) (6)	16 Mar 2021 14:37:48

US3522082

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 08:00:15

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 18:01:29
User entered '11 Mar 2021'	(b) (4), (b) (6)	16 Mar 2021 14:38:59

US3522082

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 08:00:15

Procedure/Surgery

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 18:01:29
User entered 'Bloodwork- PTT, PROTIME, PT, NT PRO BNP, MAGNESIUM, CBC W/ DIFF, BMP, WHOLE BLOOD GLUCOSE'	(b) (4), (b) (6)	16 Mar 2021 14:38:59

US3522082

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 08:00:15

Indication

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 18:01:29
User entered 'Medical History (MH)'	(b) (4), (b) (6)	16 Mar 2021 14:38:59

US3522082

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 08:00:15

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 18:01:29
User entered empty.	(b) (4), (b) (6)	16 Mar 2021 14:38:59

US3522082
Folder: SAE USA-US131-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 10 Jun 2021 08:00:15
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:13:44
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:41:38
User entered 'USA-US131-2021-MRNA-1273-P301000010'	System	05 Mar 2021 15:38:47

US3522082
Folder: SAE USA-US131-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 10 Jun 2021 08:00:15
Serious

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:13:44
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:41:38
User entered 'Yes (Y)'	System	05 Mar 2021 15:38:47

Death

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:13:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:41:38
User entered 'No (N)'	System	05 Mar 2021 15:38:47

FDA-CBER-2022-1614-0813266

US3522082

Folder: SAE USA-US131-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:00:15

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:13:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:41:38
User entered 'No (N)'	System	05 Mar 2021 15:38:47

US3522082

Folder: SAE USA-US131-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:00:15

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:13:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:41:38
User entered 'Yes (Y)'	System	05 Mar 2021 15:38:47

US3522082
Folder: SAE USA-US131-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 10 Jun 2021 08:00:15
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:13:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:41:38
User entered 'No (N)'	System	05 Mar 2021 15:38:47

US3522082

Folder: SAE USA-US131-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:00:15

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:13:44
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:41:38
User entered 'No (N)'	System	05 Mar 2021 15:38:47

US3522082

Folder: SAE USA-US131-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:00:15

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:13:44
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:41:38
User entered 'No (N)'	System	05 Mar 2021 15:38:47

US3522082
Folder: SAE USA-US131-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 10 Jun 2021 08:00:15

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:13:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:41:38
User entered 'Paul'	System	05 Mar 2021 15:38:47

US3522082
Folder: SAE USA-US131-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 10 Jun 2021 08:00:15
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:13:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:41:38
User entered 'Kilgore'	System	05 Mar 2021 15:38:47

US3522082

Folder: SAE USA-US131-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:00:15

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:13:44
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:41:38
User entered (b) (6) '	System	05 Mar 2021 15:38:47

US3522082
Folder: SAE USA-US131-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 10 Jun 2021 08:00:15
Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:13:44
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:41:38
User entered (b) (6) '	System	05 Mar 2021 15:38:47

US3522082
Folder: SAE USA-US131-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 10 Jun 2021 08:00:15
Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:13:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:41:38
User entered 'MI'	System	05 Mar 2021 15:38:47

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:13:44
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:41:38
User entered (b) (6)'	System	05 Mar 2021 15:38:47

US3522082
Folder: SAE USA-US131-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 10 Jun 2021 08:00:15
Investigator Country

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	17 Mar 2021 18:38:53
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:13:44
User entered 'US'	(b) (4) System	05 Mar 2021 15:41:46

US3522082
Folder: SAE USA-US131-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 10 Jun 2021 08:00:15
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '2'	System	17 Mar 2021 18:39:04
User entered '1'	System	05 Mar 2021 15:41:46

US3522082
Folder: SAE USA-US131-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 10 Jun 2021 08:00:15
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:13:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:41:38
User entered 'USA-US131-2021-MRNA-1273-P301000010'	System	05 Mar 2021 15:38:47

US3522082

Folder: SAE USA-US131-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:00:15

Serious

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:13:44
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:41:38
User entered 'Yes (Y)'	System	05 Mar 2021 15:38:47

Death

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:13:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:41:38
User entered 'No (N)'	System	05 Mar 2021 15:38:47

US3522082
Folder: SAE USA-US131-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 10 Jun 2021 08:00:15
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:13:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:41:38
User entered 'No (N)'	System	05 Mar 2021 15:38:47

US3522082

Folder: SAE USA-US131-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:00:15

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:13:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:41:38
User entered 'Yes (Y)'	System	05 Mar 2021 15:38:47

US3522082

Folder: SAE USA-US131-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:00:15

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:13:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:41:38
User entered 'No (N)'	System	05 Mar 2021 15:38:47

US3522082
Folder: SAE USA-US131-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 10 Jun 2021 08:00:15
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:13:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:41:38
User entered 'No (N)'	System	05 Mar 2021 15:38:47

US3522082

Folder: SAE USA-US131-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:00:15

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:13:44
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:41:38
User entered 'No (N)'	System	05 Mar 2021 15:38:47

US3522082
Folder: SAE USA-US131-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 10 Jun 2021 08:00:15

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:13:44
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:41:38
User entered 'Paul'	System	05 Mar 2021 15:38:47

US3522082
Folder: SAE USA-US131-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 10 Jun 2021 08:00:15
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:13:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:41:38
User entered 'Kilgore'	System	05 Mar 2021 15:38:47

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:13:44
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:41:38
User entered (b) (6) '	System	05 Mar 2021 15:38:47

FDA-CBER-2022-1614-0813290

US3522082
Folder: SAE USA-US131-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 10 Jun 2021 08:00:15

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:13:44
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:41:38
User entered (b) (6) '	System	05 Mar 2021 15:38:47

US3522082
Folder: SAE USA-US131-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 10 Jun 2021 08:00:15

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:13:44
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:41:38
User entered 'MI'	System	05 Mar 2021 15:38:47

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:13:44
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:41:38
User entered (b) (6) '	System	05 Mar 2021 15:38:47

US3522082
Folder: SAE USA-US131-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 10 Jun 2021 08:00:15
Investigator Country

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	17 Mar 2021 18:38:53
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:13:44
User entered 'US'	(b) (4) System	05 Mar 2021 15:41:46

US3522082
Folder: SAE USA-US131-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 10 Jun 2021 08:00:15
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '2'	System	17 Mar 2021 18:39:04
User entered '1'	System	05 Mar 2021 15:41:46

US3522082

Folder: SAE USA-US131-2021-MRNA-1273-P301000010

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:00:15

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:13:44
User entered '05/Mar/2021 15:41'	System	05 Mar 2021 15:41:46

US3522082

Folder: SAE USA-US131-2021-MRNA-1273-P301000010

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:00:15

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.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	17 Mar 2021 18:38:53
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:13:44
User entered '1'	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:41:46

US3522082
Folder: SAE USA-US131-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 10 Jun 2021 08:00:15
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:13:44
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:41:38
User entered '1JSA-US131-2021-MRNA-1273-P301000010'	System	05 Mar 2021 15:38:47

US3522082
Folder: SAE USA-US131-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 10 Jun 2021 08:00:15
Serious

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:13:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:41:38
User entered 'Yes (Y)'	System	05 Mar 2021 15:38:47

US3522082
Folder: SAE USA-US131-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 10 Jun 2021 08:00:15
Death

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:13:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:41:38
User entered 'No (N)'	System	05 Mar 2021 15:38:47

US3522082

Folder: SAE USA-US131-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:00:15

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 17:13:44
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:41:38
User entered 'No (N)'	System	05 Mar 2021 15:38:47

US3522082
Folder: SAE USA-US131-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 10 Jun 2021 08:00:15
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:13:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:41:38
User entered 'Yes (Y)'	System	05 Mar 2021 15:38:47

US3522082
Folder: SAE USA-US131-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 10 Jun 2021 08:00:15
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:13:44
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:41:38
User entered 'No (N)'	System	05 Mar 2021 15:38:47

US3522082

Folder: SAE USA-US131-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:00:15

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:13:44
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:41:38
User entered 'No (N)'	System	05 Mar 2021 15:38:47

US3522082

Folder: SAE USA-US131-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:00:15

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:13:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:41:38
User entered 'No (N)'	System	05 Mar 2021 15:38:47

US3522082
Folder: SAE USA-US131-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 10 Jun 2021 08:00:15

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:13:44
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:41:38
User entered 'Paul'	System	05 Mar 2021 15:38:47

US3522082
Folder: SAE USA-US131-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 10 Jun 2021 08:00:15
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:13:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:41:38
User entered 'Kilgore'	System	05 Mar 2021 15:38:47

US3522082

Folder: SAE USA-US131-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:00:15

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:13:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 15:41:38
User entered (b) (6) '	System	05 Mar 2021 15:38:47

US3522082
Folder: SAE USA-US131-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 10 Jun 2021 08:00:15

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:13:44
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:41:38
User entered (b) (6) '	System	05 Mar 2021 15:38:47

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:13:44
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:41:38
User entered 'MI'	System	05 Mar 2021 15:38:47

FDA-CBER-2022-1614-0813310

US3522082

Folder: SAE USA-US131-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 08:00:15

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:13:44
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 15:41:38
User entered (b) (6)'	System	05 Mar 2021 15:38:47

US3522082
Folder: SAE USA-US131-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 10 Jun 2021 08:00:15

Investigator Country

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	17 Mar 2021 18:38:53
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 17:13:44
User entered 'US'	(b) (4) System	05 Mar 2021 15:41:46

US3522082
Folder: SAE USA-US131-2021-MRNA-1273-P301000010
Form: Safety Report Form
Generated On: 10 Jun 2021 08:00:15
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '2'	System	17 Mar 2021 18:39:04
User entered '1'	System	05 Mar 2021 15:41:46

US3522082

Folder: SAE USA-US131-2021-MRNA-1273-P301000010

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:00:15

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	19 Mar 2021 18:01:29
User entered '17/Mar/2021 13:39'	System	17 Mar 2021 18:39:04

US3522082

Folder: SAE USA-US131-2021-MRNA-1273-P301000010

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:00:15

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.

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:01:29
	(b) (4)	
User entered '1'	(b) (4), (b) (6)	17 Mar 2021 18:39:04