US3192486 (Prod: Quality of Life Medical and Research Center - Hunt - PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:43:12

All time stamps listed in this document are displayed in GMT

US3192486

Form: Participant Creation

Data signed: (b) (4) **07 Apr 2021 14:37:46**

Generated On: 09 Jun 2021 15:43:12

Participant ID   US3192486

mRNA-1273-P301 Completion Guidelines

US3192486

Folder: Screening

Form: Visit Date

Data signed: (b) (4) **14 Feb 2021 03:00:05**

Generated On: 09 Jun 2021 15:43:12

Was this visit performed?	Yes ⬤
	No ◯

Visit date (dd MMM yyyy)	26 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ◯
	Clinic ⬤

Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) **14 Feb 2021 02:59:55**

Generated On: 09 Jun 2021 15:43:12

Date of Birth (MMM yyyy)	(b) (6) 1947
Age	73
Age Units	YEARS
Age (Derived)	73
Sex	Female ◯
	Male ⬤
Ethnicity	Hispanic or Latino ◯
	Not Hispanic or Latino ⬤
	Not Reported ◯
	Unknown ◯

Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) **14 Feb 2021 02:59:55**

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Date of Informed Consent *(dd MMM yyyy)*	26 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020

Protocol Version	
	Amendment 1 ⭘
	Amendment 2 ⬤
	Amendment 3 ⭘
	Amendment 4 ⭘
	Amendment 5 ⭘

Was participant enrolled in the study?	
	Yes ⬤
	No ⭘

If No, indicate reason for screen fail	
	Withdrew Consent ⭘
	Inclusion/Exclusion ⭘
	Cohort Full ⭘
	Other ⭘

If reason for screen fail is Other, specify	

Was this participant screened previously?	
	Yes ⭘
	No ⬤

If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) **14 Feb 2021 02:59:55**

Generated On: 09 Jun 2021 15:43:12

Did the participant meet all eligibility criteria?   Yes ●

No ○

Folder: Screening
Form: Medical History Summary
Data signed: (b) (4) **14 Feb 2021 02:59:55**
Generated On: 09 Jun 2021 15:43:12

Were any significant conditions reported?   Yes ●

                                                    No ○

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) **07 Apr 2021 14:38:08**

Generated On: 09 Jun 2021 15:43:12

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

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) **07 Apr 2021 14:38:08**

Generated On: 09 Jun 2021 15:43:12

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2013
Start date completely unknown	False
Condition ongoing at study entry	Yes ⬤
	No ◯
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2013
Start Year (derived)	2013
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) **07 Apr 2021 14:38:08**

Generated On: 09 Jun 2021 15:43:12

Condition	OSTEOARTHRITIS
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes ●
	No ○
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) **07 Apr 2021 14:38:08**

Generated On: 09 Jun 2021 15:43:12

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

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) **07 Apr 2021 14:38:08**

Generated On: 09 Jun 2021 15:43:12

Condition	APPENDECTOMY
Start date (dd MMM yyyy)	UN UNK 1980
Start date completely unknown	False
Condition ongoing at study entry	Yes ◯
	No ⬤
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1980
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1980
Start Year (derived)	1980
Stop Month and Year (derived)	JAN 1980
Stop Year (derived)	1980

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) **07 Apr 2021 14:38:08**

Generated On: 09 Jun 2021 15:43:12

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

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) **07 Apr 2021 14:38:08**

Generated On: 09 Jun 2021 15:43:12

Condition	LEFT KNEE ARTHROSCOPIC SURGERY
Start date (dd MMM yyyy)	UN UNK 2005
Start date completely unknown	False
Condition ongoing at study entry	Yes ⬭
	No ⬤
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2005
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	JAN 2005
Stop Year (derived)	2005

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) **07 Apr 2021 14:38:08**

Generated On: 09 Jun 2021 15:43:12

Condition	DIABETES TYPE 2
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes ⬤
	No ◯
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) **07 Apr 2021 14:38:08**

Generated On: 09 Jun 2021 15:43:12

Condition	CHRONIC PAIN
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes ●
	No ○
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) **07 Apr 2021 14:38:08**

Generated On: 09 Jun 2021 15:43:12

Condition	CHRONIC PANCRATITIS
Start date (dd MMM yyyy)	UN UNK 2005
Start date completely unknown	False
Condition ongoing at study entry	Yes ●
	No ○
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) **07 Apr 2021 14:38:08**

Generated On: 09 Jun 2021 15:43:12

Condition	ANXIETY
Start date (dd MMM yyyy)	UN UNK 1975
Start date completely unknown	False
Condition ongoing at study entry	Yes ●
	No ○
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1975
Start Year (derived)	1975
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) **07 Apr 2021 14:38:08**

Generated On: 09 Jun 2021 15:43:12

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

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) **07 Apr 2021 14:38:08**

Generated On: 09 Jun 2021 15:43:12

Condition	PERIPHERAL NEUROPATHY
Start date (dd MMM yyyy)	UN UNK 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes ⬤
	No ◯
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) **07 Apr 2021 14:38:08**

Generated On: 09 Jun 2021 15:43:12

Condition	ANEMIA
Start date (dd MMM yyyy)	UN UNK 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes ●
	No ○
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) **07 Apr 2021 14:38:08**

Generated On: 09 Jun 2021 15:43:12

Condition	POST TRAUMATIC STRESS DISORDER
Start date (dd MMM yyyy)	UN UNK 1970
Start date completely unknown	False
Condition ongoing at study entry	Yes ●
	No ○
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1970
Start Year (derived)	1970
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) **14 Feb 2021 03:00:05**

Generated On: 09 Jun 2021 15:43:12

Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	26 AUG 2020
Time of assessment *(00:00-23:59)*	08:20 (24 HR)
Vital Signs Date and Time (derived)	26 AUG 2020 08:20
Height *(xxx.x)*	71 in
Weight *(xxx.x)*	225 lb
BMI *(xxx.x)*	31.44675 kg/m^2
BMI units	KG/M2
Temperature *(xxx.x)*	ND - Not Done
Route of measurement	Oral ○
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	ND - Not Done
Pulse units	BPM
Respiratory Rate *(xxx)*	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) **14 Feb 2021 02:59:55**

Generated On: 09 Jun 2021 15:43:12

Was the physical examination performed? Yes ⬤

No ◯

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

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 14 Feb 2021 02:59:55

Generated On: 09 Jun 2021 15:43:12

Occupational Risk

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

Specify

Location and Living Circumstances Risk (check all that apply)

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) **14 Feb 2021 02:59:55**

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) **14 Feb 2021 03:00:06**

Generated On: 09 Jun 2021 15:43:12

Was this visit performed?	Yes ●
	No ○

Visit date (dd MMM yyyy)	26 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●

Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) **14 Feb 2021 03:00:06**

Generated On: 09 Jun 2021 15:43:12

What was the date of randomization? *(dd MMM yyyy)*	26 AUG 2020
What was the participant's randomization number?	188318

In what Cohort was the participant enrolled?

- >=18 and <65 years and not at risk ⚪
- >=18 and <65 years and at risk ⚪
- >=65 years ⬤

If participant is considered at risk, please check all that apply (If any are checked as Yes, please ensure the actual condition is recorded on the Medical History form)

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)	Yes	⚪
	No	⬤
Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)	Yes	⚪
	No	⬤
Severe obesity (body mass index > or = 40kg/m2)	Yes	⚪
	No	⬤
Diabetes (Type I, Type 2, or gestational)	Yes	⬤
	No	⚪
Liver Disease	Yes	⚪
	No	⬤
Human Immunodeficiency Virus (HIV) infection	Yes	⚪
	No	⬤

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) **14 Feb 2021 03:00:06**

Generated On: 09 Jun 2021 15:43:12

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) **14 Feb 2021 03:00:06**

Generated On: 09 Jun 2021 15:43:12

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ⬤
	Post-Dose ◯
Were vital signs assessed?	Yes ⬤
	No ◯
Date of assessment *(dd MMM yyyy)*	26 AUG 2020
Time of assessment *(00:00-23:59)*	08:20 (24 HR)
Vital Signs Date and Time (derived)	26 AUG 2020 08:20
Temperature *(xxx.x)*	98.7 F
Route of measurement	Oral ⬤
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	60 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	70 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4)   **14 Feb 2021 03:00:06**

Generated On: 09 Jun 2021 15:43:12

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ◯
	Post-Dose ⬤
Were vital signs assessed?	Yes ⬤
	No ◯
Date of assessment *(dd MMM yyyy)*	26 AUG 2020
Time of assessment *(00:00-23:59)*	10:21 (24 HR)
Vital Signs Date and Time (derived)	26 AUG 2020 10:21
Temperature *(xxx.x)*	97.8 F
Route of measurement	Oral ⬤
	Axillary ◯
	Other ◯
If Other, specify	
Pulse *(xxx)*	58 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	83 mmHg
Diastolic Blood Pressure units	MMHG

Folder: Visit 1 Day 1
Form: Physical Examination
Data signed: (b) (4) **14 Feb 2021 03:00:06**
Generated On: 09 Jun 2021 15:43:12

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)*	26 AUG 2020
What was the treatment time? *(00:00-23:59)*	08:58 (24 HR)
Treatment Date and Time (derived)	26 AUG 2020 08:58
Which arm was used to give treatment?	Left Arm ●
	Right Arm ○
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4)　**14 Feb 2021 03:00:06**

Generated On: 09 Jun 2021 15:43:12

Was the sample collected?	Yes ●
	No ◯
Collection date *(dd MMM yyyy)*	26 AUG 2020
Collection time *(00:00-23:59)*	08:44 (24 HR)
Collection date and time (derived)	26 AUG 2020 08:44

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) **14 Feb 2021 03:00:06**

Generated On: 09 Jun 2021 15:43:12

Collection date *(dd MMM yyyy)* 26 AUG 2020

Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:46	26 AUG 2020 08:46
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4)   **14 Feb 2021 03:00:06**

Generated On: 09 Jun 2021 15:43:12

Is the participant continuing to the next visit?   Yes ●

No ○

Continuing Flag   1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:43:12

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**	97.8 °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	26 AUG 2020 09:28
PC Open Date & Time	26 AUG 2020 09:18
PC Close Date & Time	26 AUG 2020 11:48

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Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:43:12

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**	97.8 °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	27 AUG 2020 09:40
PC Open Date & Time	26 AUG 2020 12:43
PC Close Date & Time	27 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:43:12

TIMEPOINT	DAY 2

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE** in °F	97.8 °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	28 AUG 2020 06:05
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3192486

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:43:12

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

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

To **TREAT** pain or fever that has already occurred	
To **PREVENT** pain or fever from occurring	
PC Time Stamp	
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3192486

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:43:12

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**	97.6 °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	29 AUG 2020 14:49
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

FDA-CBER-2022-1614-0414301

US3192486

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:43:12

TIMEPOINT	DAY 5

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

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

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

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

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

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

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

Please record your **TEMPERATURE in °F**	97.5 °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	31 AUG 2020 05:59
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

FDA-CBER-2022-1614-0414302

US3192486

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:43:12

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

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

To **TREAT** pain or fever that has already occurred	
To **PREVENT** pain or fever from occurring	
PC Time Stamp	
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3192486

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:43:12

TIMEPOINT	DAY 7

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

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

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

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

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

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

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

Please record your **TEMPERATURE in °F**	97.8 °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	01 SEP 2020 12:01
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3192486
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:43:12

TIMEPOINT	DAY 1, 30 MINUTES AFTER VACCINATION (AT STUDY CLINIC)
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ⬤
	Does not interfere with activity ◯
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ◯
	Any use of prescription pain reliever or prevents daily activity ◯
Is there any **REDNESS AT INJECTION SITE**?	Yes ◯
	No ⬤
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ◯
	No ⬤
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ⬤
	Does not interfere with activity ◯
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ◯
	Any use of prescription pain reliever or prevents daily activity ◯
PC Time Stamp	26 AUG 2020 09:29
PC Open Date & Time	26 AUG 2020 09:18
PC Close Date & Time	26 AUG 2020 11:48

US3192486
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:43:12

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ●
	Does not interfere with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ○
	Any use of prescription pain reliever or prevents daily activity ○
Is there any **REDNESS AT INJECTION SITE**?	Yes ○
	No ●
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ○
	No ●
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ●
	Does not interfere with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ○
	Any use of prescription pain reliever or prevents daily activity ○
PC Time Stamp	27 AUG 2020 09:40
PC Open Date & Time	26 AUG 2020 12:43
PC Close Date & Time	27 AUG 2020 11:59

TIMEPOINT	DAY 2

Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ●
	Does not interfere with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ○
	Any use of prescription pain reliever or prevents daily activity ○

Is there any **REDNESS AT INJECTION SITE**?	Yes ○
	No ●

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ○
	No ●

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

PC Time Stamp	28 AUG 2020 06:05
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3192486
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:43:12

TIMEPOINT	DAY 3

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

None ◯
Does not interfere with activity ◯
Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ◯
Any use of prescription pain reliever or prevents daily activity ◯

Is there any **REDNESS AT INJECTION SITE**?

Yes ◯
No ◯

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

_____

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.

_____

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

US3192486

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:43:12

TIMEPOINT	DAY 4

Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ●
	Does not interfere with activity ◯
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ◯
	Any use of prescription pain reliever or prevents daily activity ◯

Is there any **REDNESS AT INJECTION SITE**?	Yes ◯
	No ●

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ◯
	No ●

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

PC Time Stamp	29 AUG 2020 14:49
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3192486

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:43:12

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	31 AUG 2020 06:00
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3192486
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:43:12

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 ◯

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided. _____

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. _____

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	_____
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 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	01 SEP 2020 12:01
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3192486

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:43:12

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 ◯

US3192486

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:43:12

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

PC Time stamp	26 AUG 2020 09:29
PC Open Date & Time	26 AUG 2020 09:18
PC Close Date & Time	26 AUG 2020 11:48

US3192486

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:43:12

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)

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

FATIGUE	
None	●
No interference with activity	○
Some interference with activity	○
Significant; prevents daily activity	○

MUSCLE ACHES ALL OVER BODY	
None	●
No interference with activity	○
Some interference with activity	○
Significant; prevents daily activity	○

JOINT ACHES IN SEVERAL JOINTS	
None	●
No interference with activity	○
Some interference with activity	○
Significant; prevents daily activity	○

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

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

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

PC Time stamp	27 AUG 2020 09:41
PC Open Date & Time	26 AUG 2020 12:43
PC Close Date & Time	27 AUG 2020 11:59

US3192486
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:43:12

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	28 AUG 2020 06:06
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3192486
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:43:12

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 ◯

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

TIMEPOINT	DAY 4

HEADACHE

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

FATIGUE

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

MUSCLE ACHES ALL OVER BODY

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

JOINT ACHES IN SEVERAL JOINTS

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

NAUSEA/VOMITING

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

CHILLS

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

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

	Yes ◯
PC Time stamp	29 AUG 2020 14:50
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3192486

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:43:12

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 ⬤

PRODUCTION RELEASE (v12.003 EAB) (1725)

	Yes ◯
PC Time stamp	31 AUG 2020 06:00
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 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 ◯

FDA-CBER-2022-1614-0414325

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

US3192486

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:43:12

TIMEPOINT	DAY 7
HEADACHE	None ●
	No interference with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity ○
	Any use of prescription pain reliever or prevents daily activity ○
FATIGUE	None ●
	No interference with activity ○
	Some interference with activity ○
	Significant; prevents daily activity ○
MUSCLE ACHES ALL OVER BODY	None ●
	No interference with activity ○
	Some interference with activity ○
	Significant; prevents daily activity ○
JOINT ACHES IN SEVERAL JOINTS	None ●
	No interference with activity ○
	Some interference with activity ○
	Significant; prevents daily activity ○
NAUSEA/VOMITING	None ●
	No interference with activity or 1-2 episodes/24 hours ○
	Some interference with activity or >2 episodes/24 hours ○
	Prevents daily activity, requires outpatient IV hydration ○
CHILLS	None ●
	No interference with activity ○
	Some interference with activity not requiring medical attention ○
	Prevents daily activity and requires medical attention ○
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ●

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

US3192486

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) **14 Feb 2021 02:59:55**

Generated On: 09 Jun 2021 15:43:12

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

| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 05 SEP 2020 |

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

Comments

If Contact Not Made, please provide Comments

US3192486

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) **14 Feb 2021 02:59:55**

Generated On: 09 Jun 2021 15:43:12

Is the participant continuing to the next visit?   Yes ●

                                                                                                      No ○

Continuing Flag   1

US3192486

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) **14 Feb 2021 03:58:07**

Generated On: 09 Jun 2021 15:43:12

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

| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 09 SEP 2020 |

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

Comments

If Contact Not Made, please provide Comments

US3192486
Folder: Safety Call Day 15 (1)
Form: Continuing
Data signed: (b) (4) **14 Feb 2021 03:58:07**
Generated On: 09 Jun 2021 15:43:12

Is the participant continuing to the next visit?   Yes ⬤

No ◯

Continuing Flag   1

US3192486

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4)   **14 Feb 2021 02:59:55**

Generated On: 09 Jun 2021 15:43:12

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

| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 19 SEP 2020 |

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

Comments

If Contact Not Made, please provide Comments

US3192486

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) **14 Feb 2021 02:59:55**

Generated On: 09 Jun 2021 15:43:12

Is the participant continuing to the next visit?   Yes ●

No ○

Continuing Flag   1

US3192486

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) **14 Feb 2021 03:00:06**

Generated On: 09 Jun 2021 15:43:12

Was this visit performed?	Yes ⬤
	No ◯

Visit date (dd MMM yyyy)	23 SEP 2020

Was visit performed at the participant's home or at the clinic?	Home ◯
	Clinic ⬤

Folder OID	VISIT2

Timepoint	Pre-Dose ●
	Post-Dose ○
Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	23 SEP 2020
Time of assessment *(00:00-23:59)*	09:50 (24 HR)
Vital Signs Date and Time (derived)	23 SEP 2020 09:50
Temperature *(xxx.x)*	96.8 F
Route of measurement	Oral ●
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	52 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	142 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	87 mmHg
Diastolic Blood Pressure units	MMHG

US3192486

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) **14 Feb 2021 03:00:06**

Generated On: 09 Jun 2021 15:43:12

Timepoint	Pre-Dose ⬭
	Post-Dose ⬛
Were vital signs assessed?	Yes ⬛
	No ⬭
Date of assessment *(dd MMM yyyy)*	23 SEP 2020
Time of assessment *(00:00-23:59)*	10:40 (24 HR)
Vital Signs Date and Time (derived)	23 SEP 2020 10:40
Temperature *(xxx.x)*	98.0 F
Route of measurement	Oral ⬛
	Axillary ⬭
	Other ⬭
If Other, specify	
Pulse *(xxx)*	55 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	147 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	88 mmHg
Diastolic Blood Pressure units	MMHG

US3192486

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4)   **14 Feb 2021 03:00:06**

Generated On: 09 Jun 2021 15:43:12

Was the physical examination performed?   Yes ●

                                                                                           No ○

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

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

Folder: Visit 2 Day 29 (1)
Form: Exposure
Data signed: (b) (4) **14 Feb 2021 03:00:06**
Generated On: 09 Jun 2021 15:43:12

Was study treatment given?	Yes	●
	No	○

If No, reason not given		
	Participant declined due to Adverse Event	○
	Physician withheld dose due to Adverse Event	○
	Death	○
	Lost To Follow-Up	○
	Physician Decision	○
	Pregnancy	○
	Protocol Deviation	○
	Study Terminated by Sponsor	○
	Withdrawal of Consent by Participant	○
	Confirmed COVID-19	○
	Other	○

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment?	MRNA-1273 OR PLACEBO
What was the treatment date? *(dd MMM yyyy)*	23 SEP 2020
What was the treatment time? *(00:00-23:59)*	10:09 (24 HR)
Treatment Date and Time (derived)	23 SEP 2020 10:09
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

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) **14 Feb 2021 03:00:06**

Generated On: 09 Jun 2021 15:43:12

Was the sample collected?	Yes ●
	No ○

Collection date *(dd MMM yyyy)*	23 SEP 2020
Collection time *(00:00-23:59)*	10:00 (24 HR)
Collection date and time (derived)	23 SEP 2020 10:00

US3192486

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) **14 Feb 2021 03:00:06**

Generated On: 09 Jun 2021 15:43:12

Collection date *(dd MMM yyyy)*			23 SEP 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:05	23 SEP 2020 10:05
Nasopharyngeal Swab 2	No		

US3192486

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) **14 Feb 2021 03:00:06**

Generated On: 09 Jun 2021 15:43:12

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**	98.0 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ●
	No ◯

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

To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	23 SEP 2020 10:33
PC Open Date & Time	23 SEP 2020 10:29
PC Close Date & Time	23 SEP 2020 12:59

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**	97.8 °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	23 SEP 2020 17:32
PC Open Date & Time	23 SEP 2020 13:54
PC Close Date & Time	24 SEP 2020 11:59

US3192486

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:43:12

TIMEPOINT	DAY 2

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

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

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

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

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

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

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

Please record your **TEMPERATURE in °F**	97.2 °F

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

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

PC Time Stamp	24 SEP 2020 12:03
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3192486

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:43:12

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**	97.5 °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	25 SEP 2020 12:00
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3192486

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:43:12

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**	97.6 °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	26 SEP 2020 13:18
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3192486

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:43:12

TIMEPOINT	DAY 5

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	96.8 °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	27 SEP 2020 12:01
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3192486

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:43:12

TIMEPOINT	DAY 6

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

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

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

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

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

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

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

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

PC Time Stamp	28 SEP 2020 12:31
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3192486

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:43:12

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.
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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**	_____
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ◯ No ◯
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	_____
To **PREVENT** pain or fever from occurring	_____
PC Time Stamp	_____
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

TIMEPOINT	DAY 1, 30 MINUTES AFTER VACCINATION (AT STUDY CLINIC)
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ●
	Does not interfere with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ○
	Any use of prescription pain reliever or prevents daily activity ○
Is there any **REDNESS AT INJECTION SITE**?	Yes ○
	No ●
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ○
	No ●
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ●
	Does not interfere with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ○
	Any use of prescription pain reliever or prevents daily activity ○
PC Time Stamp	23 SEP 2020 10:34
PC Open Date & Time	23 SEP 2020 10:29
PC Close Date & Time	23 SEP 2020 12:59

US3192486

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:43:12

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ⬤ Does not interfere with activity ◯ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ◯ Any use of prescription pain reliever or prevents daily activity ◯
Is there any **REDNESS AT INJECTION SITE**?	Yes ◯ No ⬤
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ◯ No ⬤
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ⬤ Does not interfere with activity ◯ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ◯ Any use of prescription pain reliever or prevents daily activity ◯
PC Time Stamp	23 SEP 2020 17:32
PC Open Date & Time	23 SEP 2020 13:54
PC Close Date & Time	24 SEP 2020 11:59

US3192486

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:43:12

TIMEPOINT	DAY 2
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ●
	Does not interfere with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ○
	Any use of prescription pain reliever or prevents daily activity ○
Is there any **REDNESS AT INJECTION SITE**?	Yes ○
	No ●
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ○
	No ●
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ●
	Does not interfere with activity ○
	Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ○
	Any use of prescription pain reliever or prevents daily activity ○
PC Time Stamp	24 SEP 2020 12:04
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3192486

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:43:12

TIMEPOINT	DAY 3

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

- None ●
- Does not interfere with activity ○
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ○
- Any use of prescription pain reliever or prevents daily activity ○

Is there any **REDNESS AT INJECTION SITE**?

- Yes ○
- No ●

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

- Yes ○
- No ●

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

- None ●
- Does not interfere with activity ○
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ○
- Any use of prescription pain reliever or prevents daily activity ○

PC Time Stamp	25 SEP 2020 12:01
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3192486

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:43:12

TIMEPOINT	DAY 4

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

None	⬤
Does not interfere with activity	◯
Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity	◯
Any use of prescription pain reliever or prevents daily activity	◯

Is there any **REDNESS AT INJECTION SITE**?

Yes	◯
No	⬤

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Yes	◯
No	⬤

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

None	⬤
Does not interfere with activity	◯
Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity	◯
Any use of prescription pain reliever or prevents daily activity	◯

PC Time Stamp	26 SEP 2020 13:18
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 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	27 SEP 2020 12:01
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3192486

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:43:12

TIMEPOINT	DAY 6

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

- None ●
- Does not interfere with activity ○
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ○
- Any use of prescription pain reliever or prevents daily activity ○

Is there any **REDNESS AT INJECTION SITE**?

- Yes ○
- No ●

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

- Yes ○
- No ●

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

- None ●
- Does not interfere with activity ○
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ○
- Any use of prescription pain reliever or prevents daily activity ○

PC Time Stamp	28 SEP 2020 12:31
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3192486
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:43:12

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 ◯
Please record - **REDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site redness with the ruler provided.	_____
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.	_____
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	_____
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3192486

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:43:12

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 ◯

US3192486

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:43:12

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

PC Time stamp	23 SEP 2020 10:34
PC Open Date & Time	23 SEP 2020 10:29
PC Close Date & Time	23 SEP 2020 12:59

US3192486
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:43:12

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	○

US3192486

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:43:12

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

PC Time stamp	23 SEP 2020 17:32
PC Open Date & Time	23 SEP 2020 13:54
PC Close Date & Time	24 SEP 2020 11:59

US3192486

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:43:12

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	24 SEP 2020 12:04
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3192486
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:43:12

TIMEPOINT	DAY 3

HEADACHE

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

FATIGUE

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

MUSCLE ACHES ALL OVER BODY

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

JOINT ACHES IN SEVERAL JOINTS

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

NAUSEA/VOMITING

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

CHILLS

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

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

	Yes ◯
PC Time stamp	25 SEP 2020 12:01
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3192486

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:43:12

TIMEPOINT	DAY 4

HEADACHE

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

FATIGUE

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

MUSCLE ACHES ALL OVER BODY

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

JOINT ACHES IN SEVERAL JOINTS

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

NAUSEA/VOMITING

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

CHILLS

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

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

	Yes ◯
PC Time stamp	26 SEP 2020 13:18
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3192486

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:43:12

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 ●

US3192486
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:43:12

	Yes ◯
PC Time stamp	27 SEP 2020 12:01
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3192486
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:43:12

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 ●

US3192486
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:43:12

	Yes ◯
PC Time stamp	28 SEP 2020 12:31
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3192486

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:43:12

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

US3192486

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) **14 Feb 2021 02:59:55**

Generated On: 09 Jun 2021 15:43:12

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

| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 30 SEP 2020 |

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

Comments

If Contact Not Made, please provide Comments

US3192486

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) **14 Feb 2021 02:59:55**

Generated On: 09 Jun 2021 15:43:12

Is the participant continuing to the next visit?   Yes ⬤

No ◯

Continuing Flag   1

US3192486

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) **14 Feb 2021 02:59:55**

Generated On: 09 Jun 2021 15:43:12

Was Contact Attempted?	Yes ●
	No ○
Date of Contact or Contact Attempt *(dd MMM yyyy)*	10 OCT 2020
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ○

Comments

If Contact Not Made, please provide Comments

US3192486

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) **14 Feb 2021 02:59:55**

Generated On: 09 Jun 2021 15:43:12

Is the participant continuing to the next visit?   Yes ●

                                                                                                              No ◯

Continuing Flag   1

US3192486

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) **14 Feb 2021 02:59:55**

Generated On: 09 Jun 2021 15:43:12

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

Date of Contact or Contact Attempt *(dd MMM yyyy)*	14 OCT 2020
Please select one status for the follow-up contact	Contact Made ●
	Contact Not Made ○

Comments

If Contact Not Made, please provide Comments _____

US3192486

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) **14 Feb 2021 02:59:55**

Generated On: 09 Jun 2021 15:43:12

Is the participant continuing to the next visit?　　　　　　　　　　　　　Yes ⬤

　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　No ◯

Continuing Flag　　　　　　　　　　　　　　　　　　　　　　　　　　　　1

US3192486

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) **14 Feb 2021 03:00:06**

Generated On: 09 Jun 2021 15:43:12

Was this visit performed?	Yes ⬤
	No ◯

Visit date (dd MMM yyyy)	18 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ◯
	Clinic ⬤

Folder OID	VISIT3

FDA-CBER-2022-1614-0414381

US3192486

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) **14 Feb 2021 03:00:06**

Generated On: 09 Jun 2021 15:43:12

Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	18 OCT 2020
Time of assessment *(00:00-23:59)*	08:28 (24 HR)
Vital Signs Date and Time (derived)	18 OCT 2020 08:28
Temperature *(xxx.x)*	97.2 F
Route of measurement	Oral ●
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	76 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	150 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	86 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) **14 Feb 2021 03:00:06**

Generated On: 09 Jun 2021 15:43:12

Was the physical examination performed?   Yes ⬤

No ◯

Date of examination *(dd MMM yyyy)*   18 OCT 2020

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

US3192486

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) **14 Feb 2021 03:00:06**

Generated On: 09 Jun 2021 15:43:12

Was the sample collected?	Yes ●
	No ○
Collection date *(dd MMM yyyy)*	18 OCT 2020
Collection time *(00:00-23:59)*	08:37 (24 HR)
Collection date and time (derived)	18 OCT 2020 08:37

US3192486

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) **14 Feb 2021 03:00:06**

Generated On: 09 Jun 2021 15:43:12

Is the participant continuing to the next visit?   Yes ●

No ○

Continuing Flag   1

US3192486

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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 ◯

US3192486
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2020 00:01
Patient Cloud Close Date & Time	30 OCT 2020 23:59

US3192486

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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 ⃝ |

US3192486

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2020 00:01
Patient Cloud Close Date & Time	06 NOV 2020 23:59

US3192486

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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	11 NOV 2020 13:06:34
Patient Cloud Open Date & Time	09 NOV 2020 00:01
Patient Cloud Close Date & Time	13 NOV 2020 23:59

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

TIMEPOINT DAY 89

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

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

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

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

FDA-CBER-2022-1614-0414391

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

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	30 NOV 2020 18:00:36
Patient Cloud Open Date & Time	27 NOV 2020 00:01
Patient Cloud Close Date & Time	01 DEC 2020 23:59

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

TIMEPOINT   DAY 103

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

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

Symptom	
Fever (Temperature $\geq$ 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-2022-1614-0414394

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2020 00:01
Patient Cloud Close Date & Time	08 DEC 2020 23:59

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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 ◯

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2020 00:01
Patient Cloud Close Date & Time	15 DEC 2020 23:59

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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	22 DEC 2020 10:02:22
Patient Cloud Open Date & Time	18 DEC 2020 00:01
Patient Cloud Close Date & Time	22 DEC 2020 23:59

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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	28 DEC 2020 20:13:17
Patient Cloud Open Date & Time	25 DEC 2020 00:01
Patient Cloud Close Date & Time	29 DEC 2020 23:59

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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	03 JAN 2021 12:00:38
Patient Cloud Open Date & Time	01 JAN 2021 00:01
Patient Cloud Close Date & Time	05 JAN 2021 23:59

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤ Yes ◯
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 JAN 2021 06:21:19
Patient Cloud Open Date & Time	15 JAN 2021 00:01
Patient Cloud Close Date & Time	19 JAN 2021 23:59

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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	22 JAN 2021 06:20:49
Patient Cloud Open Date & Time	22 JAN 2021 00:01
Patient Cloud Close Date & Time	26 JAN 2021 23:59

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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	02 FEB 2021 12:17:41
Patient Cloud Open Date & Time	29 JAN 2021 00:01
Patient Cloud Close Date & Time	02 FEB 2021 23:59

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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	07 FEB 2021 12:01:53
Patient Cloud Open Date & Time	05 FEB 2021 00:01
Patient Cloud Close Date & Time	09 FEB 2021 23:59

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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	14 FEB 2021 12:00:36
Patient Cloud Open Date & Time	12 FEB 2021 00:01
Patient Cloud Close Date & Time	16 FEB 2021 23:59

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ◯
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 FEB 2021 06:58:18
Patient Cloud Open Date & Time	19 FEB 2021 00:01
Patient Cloud Close Date & Time	23 FEB 2021 23:59

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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	02 MAR 2021 12:00:11
Patient Cloud Open Date & Time	26 FEB 2021 00:01
Patient Cloud Close Date & Time	02 MAR 2021 23:59

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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	07 MAR 2021 16:55:35
Patient Cloud Open Date & Time	05 MAR 2021 00:01
Patient Cloud Close Date & Time	09 MAR 2021 23:59

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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	14 MAR 2021 12:36:12
Patient Cloud Open Date & Time	12 MAR 2021 00:01
Patient Cloud Close Date & Time	16 MAR 2021 23:59

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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	21 MAR 2021 12:00:36
Patient Cloud Open Date & Time	19 MAR 2021 00:01
Patient Cloud Close Date & Time	23 MAR 2021 23:59

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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	26 MAR 2021 09:25:30
Patient Cloud Open Date & Time	26 MAR 2021 00:01
Patient Cloud Close Date & Time	30 MAR 2021 23:59

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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 ◯

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Please contact your study clinic immediately. Click below to confirm that you have read this 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 APR 2021 00:01
Patient Cloud Close Date & Time	06 APR 2021 23:59

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ●
	Yes ○
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	09 APR 2021 06:21:48
Patient Cloud Open Date & Time	09 APR 2021 00:01
Patient Cloud Close Date & Time	13 APR 2021 23:59

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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	18 APR 2021 12:23:03
Patient Cloud Open Date & Time	16 APR 2021 00:01
Patient Cloud Close Date & Time	20 APR 2021 23:59

FDA-CBER-2022-1614-0414416

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤
	Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬤
	Yes ◯
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 APR 2021 06:48:35
Patient Cloud Open Date & Time	23 APR 2021 00:01
Patient Cloud Close Date & Time	27 APR 2021 23:59

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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	02 MAY 2021 12:30:38
Patient Cloud Open Date & Time	30 APR 2021 00:01
Patient Cloud Close Date & Time	04 MAY 2021 23:59

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

TIMEPOINT   DAY 257

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

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

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 ⭕

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-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-2022-1614-0414421

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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 ◯

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

TIMEPOINT　　　　　　　　　　　　　　　　　　　DAY 278

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

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

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

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

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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 ≥ 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 ⬭

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

TIMEPOINT DAY 292

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

FDA-CBER-2022-1614-0414429

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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 ◯

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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 ◯

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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 ◯

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12

TIMEPOINT DAY 320

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

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

Fever (Temperature $\geq$ 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 ⭕

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

TIMEPOINT	**DAY 327**
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ⬭
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ⬭ Yes ⬭

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

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

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

FDA-CBER-2022-1614-0414439

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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 ◯

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

TIMEPOINT	DAY 355

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

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

Fever (Temperature ≥ 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-2022-1614-0414447

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

TIMEPOINT **DAY 362**

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Date and time of submission	
Patient Cloud Open Date & Time	20 AUG 2021 00:01
Patient Cloud Close Date & Time	24 AUG 2021 23:59

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

TIMEPOINT   DAY 369

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

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

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

TIMEPOINT	**DAY 376**

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

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

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

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

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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 ◯

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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

FDA-CBER-2022-1614-0414459

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

TIMEPOINT	**DAY 404**

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

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

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

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

FDA-CBER-2022-1614-0414461

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

TIMEPOINT   DAY 418

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

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

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

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

FDA-CBER-2022-1614-0414465

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

TIMEPOINT　　　　　　　　　　　　　　　　　　　**DAY 425**

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

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

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 ◯

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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 $\geq$ 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-2022-1614-0414469

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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 $\geq$ 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 ◯

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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

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

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

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

FDA-CBER-2022-1614-0414473

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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):

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 ◯

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

TIMEPOINT **DAY 460**

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

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

Symptom	
Fever (Temperature $\geq$ 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 ⬭

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

TIMEPOINT	**DAY 467**

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

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

Fever (Temperature ≥ 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 ◯

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

TIMEPOINT	DAY 474

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

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

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

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

FDA-CBER-2022-1614-0414481

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

TIMEPOINT	**DAY 481**

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

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

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

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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 ◯

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

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

TIMEPOINT	DAY 495

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

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

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

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

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

Fever (Temperature ≥ 100.4°F/38°C)

Chills

Cough

Shortness of breath

Difficulty breathing

Fatigue

Muscle aches

Body aches

Headache

New loss of taste

New loss of smell

Sore throat

Congestion

Runny nose

Nausea

Vomiting

Diarrhea

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

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

FDA-CBER-2022-1614-0414487

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

TIMEPOINT	DAY 502

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

TIMEPOINT	**DAY 509**

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

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

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

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

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

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

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

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

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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 ◯

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12

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

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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 ◯

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

TIMEPOINT	DAY 530

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

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

Fever (Temperature ≥ 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-2022-1614-0414497

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

TIMEPOINT　　　　　　　　　　　　　　　　　　　　　　　　　　**DAY 537**

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

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

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

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

FDA-CBER-2022-1614-0414499

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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 ⃝

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-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-2022-1614-0414503

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

TIMEPOINT DAY 558

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

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

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

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

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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 ⃝

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12

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

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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):

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

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

FDA-CBER-2022-1614-0414509

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

TIMEPOINT DAY 579

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

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

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 ⃝

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

TIMEPOINT	DAY 586

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

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

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

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

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

TIMEPOINT	DAY 600

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

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

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

FDA-CBER-2022-1614-0414517

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ◯
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ◯ Yes ◯

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

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

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

FDA-CBER-2022-1614-0414519

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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 ◯

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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):

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 ◯

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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

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

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

FDA-CBER-2022-1614-0414527

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

TIMEPOINT	DAY 642

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

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

Fever (Temperature ≥ 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 ◯

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

TIMEPOINT   DAY 649

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

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

Symptom	
Fever (Temperature $\geq$ 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-2022-1614-0414531

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

TIMEPOINT   DAY 656

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

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

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

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

FDA-CBER-2022-1614-0414533

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

TIMEPOINT	**DAY 663**

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

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

Fever (Temperature $\geq$ 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-2022-1614-0414535

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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 ◯

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

TIMEPOINT	**DAY 677**

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

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

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

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

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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 ◯

FDA-CBER-2022-1614-0414541

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

TIMEPOINT	DAY 691

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

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

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

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

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

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

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

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

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

TIMEPOINT	DAY 698

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

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

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

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

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

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

TIMEPOINT DAY 705

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

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

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

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

FDA-CBER-2022-1614-0414547

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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 ◯

FDA-CBER-2022-1614-0414549

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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 $\geq$ 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-2022-1614-0414551

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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):

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 ◯

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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 ⬭

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

TIMEPOINT	**DAY 747**

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

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

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-2022-1614-0414559

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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

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

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

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

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

TIMEPOINT	**DAY 761**

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

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

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

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

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

TIMEPOINT   DAY 768

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

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

Fever (Temperature ≥ 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 ◯

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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 ⬭

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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):

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 ◯

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

TIMEPOINT	**DAY 789**

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

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

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

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

FDA-CBER-2022-1614-0414571

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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

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

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

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

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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

US3192486

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:43:12

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		21 MAR 2021 12:01:00

US3192486

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) **09 Mar 2021 17:23:38**

Generated On: 09 Jun 2021 15:43:12

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

| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 19 NOV 2020 |

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

Comments

If Contact Not Made, please provide Comments _____

US3192486

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) **09 Mar 2021 17:23:37**

Generated On: 09 Jun 2021 15:43:12

Is the participant continuing to the next visit?   Yes ⬤

No ◯

Continuing Flag   1

US3192486
Folder: Safety Call Day 119 (1)
Form: Safety Call
Data signed: (b) (4) **07 Apr 2021 14:37:47**
Generated On: 09 Jun 2021 15:43:12

Was Contact Attempted?   Yes ●

                                                                                            No ◯

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

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

                                                                          Contact Not Made ◯

Comments

If Contact Not Made, please provide Comments

US3192486

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) **07 Apr 2021 14:37:47**

Generated On: 09 Jun 2021 15:43:12

Is the participant continuing to the next visit? Yes ●

No ○

Continuing Flag 1

US3192486

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) **07 Apr 2021 14:37:47**

Generated On: 09 Jun 2021 15:43:12

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

| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 22 JAN 2021 |

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

Comments

If Contact Not Made, please provide Comments

US3192486

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) **07 Apr 2021 14:37:47**

Generated On: 09 Jun 2021 15:43:12

Is the participant continuing to the next visit?
Yes ●

No ◯

Continuing Flag
1

US3192486

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) **07 Apr 2021 14:38:08**

Generated On: 09 Jun 2021 15:43:12

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

| Date of Contact or Contact Attempt *(dd MMM yyyy)* | 23 FEB 2021 |

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

Comments

If Contact Not Made, please provide Comments

US3192486

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) **07 Apr 2021 14:37:47**

Generated On: 09 Jun 2021 15:43:12

Is the participant continuing to the next visit?   Yes ●

No ◯

Continuing Flag   1

US3192486

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) **07 Apr 2021 14:38:09**

Generated On: 09 Jun 2021 15:43:12

Was this visit performed?	Yes ●
	No ○

Visit date (dd MMM yyyy)	12 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●

Folder OID	VISIT4

US3192486

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) **07 Apr 2021 14:38:09**

Generated On: 09 Jun 2021 15:43:12

Were vital signs assessed?	Yes ●
	No ○
Date of assessment *(dd MMM yyyy)*	12 MAR 2021
Time of assessment *(00:00-23:59)*	08:25 (24 HR)
Vital Signs Date and Time (derived)	12 MAR 2021 08:25
Temperature *(xxx.x)*	98.4 F
Route of measurement	Oral ●
	Axillary ○
	Other ○
If Other, specify	
Pulse *(xxx)*	64 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	100 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	64 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3192486

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) **07 Apr 2021 14:38:09**

Generated On: 09 Jun 2021 15:43:12

Was the physical examination performed?   Yes ●

No ◯

Date of examination *(dd MMM yyyy)*   12 MAR 2021

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

US3192486

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) **07 Apr 2021 14:38:09**

Generated On: 09 Jun 2021 15:43:12

Was the sample collected?	Yes ●
	No ○
Collection date *(dd MMM yyyy)*	12 MAR 2021
Collection time *(00:00-23:59)*	08:48 (24 HR)
Collection date and time (derived)	12 MAR 2021 08:48

US3192486

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) **07 Apr 2021 14:38:09**

Generated On: 09 Jun 2021 15:43:12

Is the participant continuing to the next visit?   Yes ●

                                                                    No ○

Continuing Flag   1

US3192486
Folder: Safety Call Day 239 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:43:12

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 _____

US3192486

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:43:12

Is the participant continuing to the next visit?   Yes ◯

                                                                          No ◯

Continuing Flag

US3192486
Folder: Covid-19 Assessment (1)
Form: COVID-19 Contact
Generated On: 09 Jun 2021 15:43:12

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	

Type of Contact	
	Clinic Visit - Scheduled ◯
	Clinical Visit - Unscheduled ◯
	Safety Call ◯
	Convalescent Tele-visit ◯

Has the subject reported symptoms of SARS-COV-2?	Yes ◯
	No ◯

Generate Next COVID-19 Assessment   Yes $\bigcirc$

No $\bigcirc$

US3192486

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

Form: Visit Date

Data signed: (b) (4) **07 Apr 2021 14:37:47**

Generated On: 09 Jun 2021 15:43:12

Was this visit performed?	Yes ●
	No ○

Visit date (dd MMM yyyy)	26 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home ○
	Clinic ●

Folder OID	UNBLND_DECIDE

US3192486

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

Form: Unblinding

Data signed: (b) (4) **12 Apr 2021 17:57:18**

Generated On: 09 Jun 2021 15:43:12

Date of updated informed consent *(dd MMM yyyy)*	26 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)*	26 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	

US3192486

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

Form: Immunogenicity Assessment

Data signed: (b) (4) **07 Apr 2021 14:37:47**

Generated On: 09 Jun 2021 15:43:12

Was the sample collected?	Yes ⬤
	No ◯
Collection date *(dd MMM yyyy)*	26 JAN 2021
Collection time *(00:00-23:59)*	15:11 (24 HR)
Collection date and time (derived)	26 JAN 2021 15:11

US3192486

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) **07 Apr 2021 14:37:47**

Generated On: 09 Jun 2021 15:43:12

Was the sample collected?	Yes ⬤
	No ◯
Collection date *(dd MMM yyyy)*	26 JAN 2021
Collection time *(00:00 - 23:59)*	14:28
Collection Date and Time (derived)	26 JAN 2021 14:28

US3192486

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) **09 Mar 2021 16:25:15**

Generated On: 09 Jun 2021 15:43:12

Did the participant experience any adverse events?   Yes ●

No ◯

If Yes, enter details on the Adverse Events form.

US3192486

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) **30 Apr 2021 20:43:25**

Generated On: 09 Jun 2021 15:43:12

AEID	USA-US097-2020-MRNA-1273-P30 1000006
Adverse event	GASTROINTESTINAL BLEED

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)*	02 NOV 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	

Ongoing?　　Yes ○　No ●

If not Ongoing, end date *(dd MMM yyyy)*	08 NOV 2020
End time *(00:00-23:59)*	
AE End Date and Time (derived)	

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

Is the adverse event serious?　　Yes ●　No ○

AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date *(dd MMM yyyy)*	02 NOV 2020
Hospital Discharge Date *(dd MMM yyyy)*	08 NOV 2020

Admitted to ICU?　　Yes ○　No ●　Unknown ○

US3192486

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) **30 Apr 2021 20:43:25**

Generated On: 09 Jun 2021 15:43:12

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	False
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

US3192486

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) **30 Apr 2021 20:43:25**

Generated On: 09 Jun 2021 15:43:12

SUBJECT WENT IN FOR
SCHEDULED COLONOSCOPY
AND ENDOSCOPY WERE IT
WAS NOTED HIS LEGS WERE
SWOLLEN AND HE WAS GIVEN
HEPARIN WHICH MADE HIM
HAVE THE GI BLEED FROM THE
COLONOSCOPY.

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

US3192486

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4)   **30 Apr 2021 20:43:25**

Generated On: 09 Jun 2021 15:43:12

AEID	USA-US097-2020-MRNA-1273-P30 1000006
Adverse event	PULMONARY EMBOLISM
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)*	2 NOV 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ◯ No ⬤
If not Ongoing, end date *(dd MMM yyyy)*	08 NOV 2020
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ◯ Grade 2/Moderate ◯ Grade 3/Severe ◯ Grade 4 ⬤
Is the adverse event serious?	Yes ⬤ No ◯

AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date *(dd MMM yyyy)*	02 NOV 2020
Hospital Discharge Date *(dd MMM yyyy)*	08 NOV 2020
Admitted to ICU?	Yes ⬤ No ◯ Unknown ◯

Number of Days in ICU	7
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False

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

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

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

Other action taken (check all that apply)

None	False
Concomitant Medication	True
Concomitant Procedure	False

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

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

Narrative	PATIENT WAS DIAGNOSED WITH PULMONARY EMBOLISM DURING COLONOSCOPY/ENDOSCOPY PROCEDURE.
Serious Adverse Event Derived (CSA Programming Field Ony)	1
Medically Attended AE Derived (CSA Programming Field Only)	1

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Admitted to ICU Derived (CSA Programming Field Only)   1

US3192486

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) **30 Apr 2021 20:43:25**

Generated On: 09 Jun 2021 15:43:12

AEID	USA-US097-2020-MRNA-1273-P30 1000006
Adverse event	DEEP VEIN THROMBOSIS

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)*   2 NOV 2020

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

AE start date and time (derived)

Ongoing?   Yes ○   No ●

  If not Ongoing, end date *(dd MMM yyyy)*   08 NOV 2020

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

AE End Date and Time (derived)

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

Is the adverse event serious?   Yes ●   No ○

AE is serious due To (check all that apply)

Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date *(dd MMM yyyy)*	02 NOV 2020
Hospital Discharge Date *(dd MMM yyyy)*	08 NOV 2020

  Admitted to ICU?   Yes ●   No ○   Unknown ○

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FDA-CBER-2022-1614-0414604

US3192486

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 30 Apr 2021 20:43:25

Generated On: 09 Jun 2021 15:43:12

Number of Days in ICU	7
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False

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

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

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

Other action taken (check all that apply)

None	False
Concomitant Medication	True
Concomitant Procedure	False

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

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	PATIENT WAS DIAGNOSED WITH DVT DURING COLONOSCOPY/ENDOSCOPY PROCEDURE.
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)	1

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) **07 Apr 2021 14:37:47**

Generated On: 09 Jun 2021 15:43:12

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

                                                                           No ◯

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

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4)   **07 Apr 2021 14:37:46**

Generated On: 09 Jun 2021 15:43:12

Name of Medication	LEVOTHYROXIN

Prophylaxis

- Yes ◯
- No ⬤

Indication	HYPOTHYROIDISM
Dose per administration	150

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 (1)
Data signed: (b) (4) **07 Apr 2021 14:37:46**
Generated On: 09 Jun 2021 15:43:12

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

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

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) **07 Apr 2021 14:37:46**

Generated On: 09 Jun 2021 15:43:12

Name of Medication	METFORMIN

Prophylaxis	Yes	⚪
	No	⚫

Indication	DIABETES TYPE 2
Dose per administration	500

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

If dose unit is Other, specify	

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

If frequency is Other, specify	

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

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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)*	UN UNK 2019
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 ⬤

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) **07 Apr 2021 14:37:46**

Generated On: 09 Jun 2021 15:43:12

Name of Medication	LISINOPRIL

Prophylaxis	Yes ●
	No ○

Indication	HYPERTENSION
Dose per administration	10

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

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration	Oral ●
	Topical ○
	Subcutaneous ○
	Transdermal ○
	Intraocular ○

PRODUCTION RELEASE (v12.003
EAB) (1725)

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

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 2015
Start date completely unknown	False
Ongoing?	Yes ●
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ●
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ●

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) **07 Apr 2021 14:37:46**

Generated On: 09 Jun 2021 15:43:12

Name of Medication	OXYCODONE
Prophylaxis	Yes ●
	No ○
Indication	CHRONIC PAIN
Dose per administration	5
Dose unit	mg ●
	ug ○
	mL ○
	g ○
	IU ○
	tablet ○
	capsule ○
	puff ○
	Other ○
If dose unit is Other, specify	
Frequency	once daily ○
	twice daily ○
	three times daily ○
	four times daily ○
	every other day ○
	every week ○
	every month ○
	as needed ●
	once ○
	unknown ○
	other ○
If frequency is Other, specify	
Route of administration	Oral ●
	Topical ○
	Subcutaneous ○
	Transdermal ○
	Intraocular ○

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

If route of administration is Other, specify

Start date *(dd MMM yyyy)*   UN UNK 2018

Start date completely unknown   False

Ongoing?   Yes ●

                                                                               No ◯

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

Was this medication taken for solicited event?   Yes ◯

                                                                               No ●

Separate Dosage Number (derived)

Interval Dosage Unit Number (derived)

Interval Dosage Definition (derived)   802 ◯

                                                                           803 ◯

                                                                           804 ◯

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) **07 Apr 2021 14:37:46**

Generated On: 09 Jun 2021 15:43:12

Name of Medication	CELEBREX
Prophylaxis	Yes ⬭
	No ⬤
Indication	OSTEOARTHRITIS
Dose per administration	100
Dose unit	mg ⬤
	ug ⬭
	mL ⬭
	g ⬭
	IU ⬭
	tablet ⬭
	capsule ⬭
	puff ⬭
	Other ⬭
If dose unit is Other, specify	
Frequency	once daily ⬭
	twice daily ⬤
	three times daily ⬭
	four times daily ⬭
	every other day ⬭
	every week ⬭
	every month ⬭
	as needed ⬭
	once ⬭
	unknown ⬭
	other ⬭
If frequency is Other, specify	
Route of administration	Oral ⬤
	Topical ⬭
	Subcutaneous ⬭
	Transdermal ⬭
	Intraocular ⬭

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

If route of administration is Other, specify

Start date *(dd MMM yyyy)*	UN UNK 2010
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 ⬤

FDA-CBER-2022-1614-0414616

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) **07 Apr 2021 14:37:46**

Generated On: 09 Jun 2021 15:43:12

Name of Medication	FLU SHOT

Prophylaxis	Yes ●
	No ○

Indication	FLU PREVENTION

Dose per administration	0.5

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 ○

PRODUCTION RELEASE (v12.003
EAB) (1725)

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Data signed: (b) (4) **07 Apr 2021 14:37:46**
Generated On: 09 Jun 2021 15:43:12

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

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	16 OCT 2020
Start date completely unknown	False
Ongoing?	Yes ◯
	No ⬤
If not Ongoing, End date *(dd MMM yyyy)*	16 OCT 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 (7)

Data signed: (b) (4) **07 Apr 2021 14:37:46**

Generated On: 09 Jun 2021 15:43:12

Name of Medication	COUMADIN
Prophylaxis	Yes ⚪
	No ⬤
Indication	TREATMENT OF PULMONARY EMBOLISM AND DEEP VEIN THROMBOSIS
Dose per administration	7.5
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)*	3 NOV 2020
Start date completely unknown	False
Ongoing?	Yes ⬤
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ⬤

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) **07 Apr 2021 14:37:46**

Generated On: 09 Jun 2021 15:43:12

Name of Medication	HEPARIN

Prophylaxis

Yes ◯
No ⬤

Indication	TREATMENT OF PULMONARY EMBOLISM AND DEEP VEIN THROMBOSIS
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 ◯

PRODUCTION RELEASE (v12.003
EAB) (1725)

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Data signed: (b) (4) **07 Apr 2021 14:37:46**
Generated On: 09 Jun 2021 15:43:12

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)*	2 NOV 2020
Start date completely unknown	False
Ongoing?	Yes ○
	No ●
If not Ongoing, End date *(dd MMM yyyy)*	3 NOV 2020
Was this medication taken for solicited event?	Yes ○
	No ●
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ○
	803 ○
	804 ○

Name of Medication	PANTOPRAZOLE

Prophylaxis	Yes ◯
	No ●

Indication	GASTROESOPHAGEAL REFLUX DISEASE

Dose per administration	40

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

If dose unit is Other, specify	

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

If frequency is Other, specify	

Route of administration	Oral ●
	Topical ◯
	Subcutaneous ◯
	Transdermal ◯

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

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 2018
Start date completely unknown	False
Ongoing?	Yes ⬤
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ⬤

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) **07 Apr 2021 14:37:46**

Generated On: 09 Jun 2021 15:43:12

Name of Medication	PREGABALIN

Prophylaxis	Yes	○
	No	●

Indication	PERIPHERAL NEUROPATHY/CHRONIC PAIN

Dose per administration	75

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

If dose unit is Other, specify	

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

If frequency is Other, specify	

Route of administration	Oral	●
	Topical	○
	Subcutaneous	○
	Transdermal	○

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

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 2019
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)	3
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 (11)

Data signed: (b) (4) **07 Apr 2021 14:37:46**

Generated On: 09 Jun 2021 15:43:12

Name of Medication	BUSPIRONE

Prophylaxis	Yes ○
	No ●

Indication	ANXIETY
Dose per administration	5

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

If dose unit is Other, specify	

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

If frequency is Other, specify	

Route of administration	Oral ●
	Topical ○
	Subcutaneous ○
	Transdermal ○
	Intraocular ○

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) **07 Apr 2021 14:37:46**

Generated On: 09 Jun 2021 15:43:12

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

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 2018
Start date completely unknown	False
Ongoing?	Yes ⬤
	No ◯

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

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

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) **07 Apr 2021 14:37:46**

Generated On: 09 Jun 2021 15:43:12

Name of Medication	FERROUS SULFATE

Prophylaxis	Yes	◯
	No	⬤

Indication	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)*	UN UNK 2019
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 (13)

Data signed: (b) (4) **07 Apr 2021 14:37:46**

Generated On: 09 Jun 2021 15:43:12

Name of Medication	QUETIAPINE

Prophylaxis

Yes ◯

No ⬤

Indication	POST TRAUMATIC STRESS DISORDER
Dose per administration	25

Dose unit

mg ⬤

ug ◯

mL ◯

g ◯

IU ◯

tablet ◯

capsule ◯

puff ◯

Other ◯

If dose unit is Other, specify _____

Frequency

once daily ◯

twice daily ◯

three times daily ⬤

four times daily ◯

every other day ◯

every week ◯

every month ◯

as needed ◯

once ◯

unknown ◯

other ◯

If frequency is Other, specify _____

Route of administration

Oral ⬤

Topical ◯

Subcutaneous ◯

Transdermal ◯

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

If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 2018
Start date completely unknown	False
Ongoing?	Yes ⬤
	No ◯
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ◯
	No ⬤
Separate Dosage Number (derived)	3
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ◯
	803 ◯
	804 ⬤

FDA-CBER-2022-1614-0414632

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) **07 Apr 2021 14:37:46**

Generated On: 09 Jun 2021 15:43:12

Name of Medication	DIVALPROEX
Prophylaxis	Yes ⚪
	No ⬤
Indication	POST TRAUMATIC STRESS DISORDER
Dose per administration	250
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 ⚪

PRODUCTION RELEASE (v12.003 EAB) (1725)

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

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

US3192486

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) **07 Apr 2021 14:37:47**

Generated On: 09 Jun 2021 15:43:12

Were any concomitant procedures performed?   Yes ●

                                                     No ◯

If yes, please complete Concomitant Procedures form.

US3192486

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) **13 Apr 2021 15:09:23**

Generated On: 09 Jun 2021 15:43:12

Procedure/Surgery date (*dd MMM yyyy*)	Procedure/Surgery	Indication	If indication is Other, specify
3 NOV 2020	BLOOD TRANSFUSION	Adverse Event	
02 NOV 2020	COLONOSCOPY	Diagnostic	
02 NOV 2020	ENDOSCOPY	Diagnostic	
02 NOV 2020	PANCREATIC STENT PLACEMENT	Adverse Event	

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 ◯

US3192486

Folder: SAE USA-US097-2020-MRNA-1273-P301000006

Form: Safety Report Form

Data signed: (b) (4) **30 Apr 2021 19:41:54**

Generated On: 09 Jun 2021 15:43:12

SAEID	USA-US097-2020-MRNA-1273-P30 1000006
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	JOHN
Investigator's Last Name	MCGETTIGAN
Site Address: Street	5390 E. ERICKSON DRIVE
Site Address: City	TUCSON
Site Address: State	AZ
Site Address: Postal Code	85712
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5

US3192486

Folder: SAE USA-US097-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Data signed: (b) (4) **30 Apr 2021 19:41:54**

Generated On: 09 Jun 2021 15:43:12

SAEID	USA-US097-2020-MRNA-1273-P30 1000006
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	JOHN
Investigator's Last Name	MCGETTIGAN
Site Address: Street	5390 E. ERICKSON DRIVE
Site Address: City	TUCSON
Site Address: State	AZ
Site Address: Postal Code	85712
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	23/NOV/2020 20:58
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Folder: SAE USA-US097-2020-MRNA-1273-P301000006

Form: Safety Report Form (2)

Data signed: (b) (4) **30 Apr 2021 19:41:54**

Generated On: 09 Jun 2021 15:43:12

SAEID	USA-US097-2020-MRNA-1273-P30 1000006
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	JOHN
Investigator's Last Name	MCGETTIGAN
Site Address: Street	5390 E. ERICKSON DRIVE
Site Address: City	TUCSON
Site Address: State	AZ
Site Address: Postal Code	85712
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	28/DEC/2020 13:58
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3192486
Folder: SAE USA-US097-2020-MRNA-1273-P301000006
Form: Safety Report Form (3)
Data signed: (b) (4) **30 Apr 2021 19:41:54**
Generated On: 09 Jun 2021 15:43:12

SAEID	USA-US097-2020-MRNA-1273-P30 1000006
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	JOHN
Investigator's Last Name	MCGETTIGAN
Site Address: Street	5390 E. ERICKSON DRIVE
Site Address: City	TUCSON
Site Address: State	AZ
Site Address: Postal Code	85712
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	26/MAR/2021 09:11
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Folder: SAE USA-US097-2020-MRNA-1273-P301000006
Form: Safety Report Form (4)
Data signed: (b) (4) **30 Apr 2021 19:41:54**
Generated On: 09 Jun 2021 15:43:12

SAEID	USA-US097-2020-MRNA-1273-P30 1000006
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	JOHN
Investigator's Last Name	MCGETTIGAN
Site Address: Street	5390 E. ERICKSON DRIVE
Site Address: City	TUCSON
Site Address: State	AZ
Site Address: Postal Code	85712
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	05/APR/2021 13:34
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

US3192486
Folder: SAE USA-US097-2020-MRNA-1273-P301000006
Form: Safety Report Form (5)
Data signed: (b) (4) **30 Apr 2021 19:41:54**
Generated On: 09 Jun 2021 15:43:12

SAEID	USA-US097-2020-MRNA-1273-P30 1000006
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	JOHN
Investigator's Last Name	MCGETTIGAN
Site Address: Street	5390 E. ERICKSON DRIVE
Site Address: City	TUCSON
Site Address: State	AZ
Site Address: Postal Code	85712
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	30/APR/2021 11:49
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

US3192486 (Prod: Quality of Life Medical and Research Center - Hunt - PPDS)

US3192486

Form: Participant Creation

Generated On: 09 Jun 2021 15:43:12

Participant ID

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'US3192486'	RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 15:34:51

US3192486
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 15:43:12

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered 'Yes (Y)'	Tianna Young (b) (4) (b) (4)	26 Aug 2020 16:07:23

US3192486
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 15:43:12

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered '26 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 15:34:52

US3192486

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered 'Clinic (Clinic)'	Tianna Young (b) (4) (b) (4)	26 Aug 2020 16:07:23

US3192486
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 15:43:12
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User entered 'SCRN'	System	26 Aug 2020 16:07:23

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US3192486

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:43:12

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered (b) (6) 1947'	RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 15:34:53

US3192486

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:43:12

Age

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered '73'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:07:15

US3192486
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 15:43:12
Age Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User entered 'YEARS'	System	29 Aug 2020 23:07:15

US3192486

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:43:12

Age (Derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User entered '73'	System	26 Aug 2020 16:07:37

US3192486

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:43:12

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered 'Male (M)'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:07:15

US3192486
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 15:43:12
Ethnicity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:07:15

US3192486

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:43:12

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered '1'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:07:15

US3192486

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:43:12

Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered '0'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:07:15

US3192486
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 15:43:12
Asian

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered '0'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:07:15

US3192486

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:43:12

American Indian or Alaska Native

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered '0'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:07:15

US3192486

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:43:12

Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered '0'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:07:15

US3192486

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:43:12

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered '0'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:07:15

US3192486

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:43:12

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered empty.	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:07:15

US3192486
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 15:43:12
Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered '0'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:07:15

US3192486
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 15:43:12
Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered '0'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:07:15

US3192486

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:43:12

Date of Informed Consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered '26 Aug 2020'	Tianna Young (b) (4) (b) (4)	26 Aug 2020 16:07:37

US3192486

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:43:12

Month and Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User entered 'Aug 2020'	System	26 Aug 2020 16:07:37

US3192486

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:43:12

Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User entered '2020'	System	26 Aug 2020 16:07:37

FDA-CBER-2022-1614-0414667

US3192486
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 15:43:12
Protocol Version

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered 'Amendment 2 (2)'	Tianna Young (b) (4) (b) (4)	26 Aug 2020 16:07:37

US3192486

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:43:12

Was participant enrolled in the study?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered 'Yes (Y)'	Tianna Young (b) (4) (b) (4)	26 Aug 2020 16:07:37

US3192486

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:43:12

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered empty.	Tianna Young (b) (4) (b) (4)	26 Aug 2020 16:07:37

US3192486

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:43:12

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered empty.	Tianna Young (b) (4) (b) (4)	26 Aug 2020 16:07:37

US3192486

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:43:12

Was this participant screened previously?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered 'No (N)'	Tianna Young (b) (4) (b) (4)	26 Aug 2020 16:07:37

US3192486

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:43:12

If Yes, previous participant number

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 15:34:52

US3192486

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:43:12

Enrollment Trigger

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User entered '1'	System	26 Aug 2020 16:07:42

US3192486

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:43:12

Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered 'Yes (Y)'	Tianna Young (b) (4) (b) (4)	26 Aug 2020 16:07:42

US3192486

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:43:12

Were any significant conditions reported?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered 'Yes (Y)'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:10:14

US3192486

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:43:12

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Aug 2020 23:25:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Aug 2020 23:25:48
Data point term sent to Coder	System	29 Aug 2020 23:24:51
User entered 'hypothyroidism'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:24:32

US3192486

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:43:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered 'un UNK 2017'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:24:32

US3192486

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:43:12

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered '0'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:24:32

US3192486

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:43:12

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered 'Yes (Y)'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:24:32

US3192486

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered empty.	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:24:32

US3192486

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:43:12

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered '0'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:24:32

US3192486

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:43:12

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User entered 'Jan 2017'	System	29 Aug 2020 23:24:32

US3192486

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:43:12

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User entered '2017'	System	29 Aug 2020 23:24:32

US3192486

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:43:12

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User entered empty.	System	29 Aug 2020 23:24:32

US3192486
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 15:43:12

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User entered empty.	System	29 Aug 2020 23:24:32

US3192486

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:43:12

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Aug 2020 23:26:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Aug 2020 23:26:48
Data point term sent to Coder	System	29 Aug 2020 23:25:52
User entered 'Hypertension'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:25:31

US3192486

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:43:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered 'un UNK 2013'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:25:31

US3192486

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:43:12

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered '0'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:25:31

US3192486

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:43:12

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered 'Yes (Y)'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:25:31

US3192486

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered empty.	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:25:31

US3192486

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:43:12

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered '0'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:25:31

US3192486

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:43:12

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User entered 'Jan 2013'	System	29 Aug 2020 23:25:31

US3192486

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:43:12

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User entered '2013'	System	29 Aug 2020 23:25:31

US3192486

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:43:12

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User entered empty.	System	29 Aug 2020 23:25:31

US3192486
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 15:43:12

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User entered empty.	System	29 Aug 2020 23:25:31

US3192486

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:43:12

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User closed query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis) and the location. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	10 Oct 2020 11:42:16
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Sep 2020 23:17:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Sep 2020 23:17:37
Data point term sent to Coder	System	18 Sep 2020 23:16:25
Query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis) and the location. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'UPDATED ' (Site from DM).	Norma Barrientos (b) (4) (b) (4)	18 Sep 2020 23:15:58
Coding entries removed.	Norma Barrientos (b) (4) (b) (4)	18 Sep 2020 23:15:51
User entered 'OSTEOARTHRITIS' reason for change: Data Entry Error	Norma Barrientos (b) (4) (b) (4)	18 Sep 2020 23:15:51
User opened query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis) and the location. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 14:22:58
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Arthropathies NEC, PT: Arthritis, LLT: Arthritis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Aug 2020 23:27:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Aug 2020 23:27:48

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Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:43:12

Condition

Audit	User	Time (GMT)
Data point term sent to Coder	System	29 Aug 2020 23:26:52
User entered 'Arthritis'	Norma Barrientos (b) (4)	29 Aug 2020 23:26:07
	(b) (4)	

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Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:43:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered 'un UNK 2010'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:26:07

US3192486

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:43:12

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered '0'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:26:07

US3192486

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:43:12

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered 'Yes (Y)'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:26:07

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Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered empty.	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:26:07

US3192486

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:43:12

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered '0'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:26:07

US3192486

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:43:12

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User entered 'Jan 2010'	System	29 Aug 2020 23:26:07

US3192486

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:43:12

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User entered '2010'	System	29 Aug 2020 23:26:07

US3192486

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:43:12

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User entered empty.	System	29 Aug 2020 23:26:07

US3192486
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 15:43:12

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User entered empty.	System	29 Aug 2020 23:26:07

US3192486
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 15:43:12
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	10 Oct 2020 11:42:39
User coded data point as SOC: Surgical and medical procedures, HLGT: Hepatobiliary therapeutic procedures, HLT: Biliary tract and gallbladder therapeutic procedures, PT: Cholecystectomy, LLT: Cholecystectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Sep 2020 23:19:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Sep 2020 23:19:38
Data point term sent to Coder	System	18 Sep 2020 23:18:26
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' answered with 'UPDATED ' (Site from DM).	Norma Barrientos (b) (4) (b) (4)	18 Sep 2020 23:17:43
Coding entries removed.	Norma Barrientos (b) (4) (b) (4)	18 Sep 2020 23:17:37
User entered 'cholecystectomy' reason for change: Data Entry Error	Norma Barrientos (b) (4) (b) (4)	18 Sep 2020 23:17:37
User coded data point as SOC: Surgical and medical procedures, HLGT: Hepatobiliary therapeutic procedures, HLT: Biliary tract and gallbladder therapeutic procedures, PT: Cholecystectomy, LLT: Gallbladder removal - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Sep 2020 19:10:48
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Sep 2020 19:10:48
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 14:22:43

US3192486

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:43:12

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Hepatobiliary therapeutic procedures, HLT: Biliary tract and gallbladder therapeutic procedures, PT: Cholecystectomy, LLT: Cholecystectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Aug 2020 23:42:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Aug 2020 23:42:40
Data point term sent to Coder	System	29 Aug 2020 23:26:52
User entered 'Gall Bladder Removal'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:26:31

US3192486

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:43:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered 'un UNK 2000'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:26:31

US3192486

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:43:12

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered '0'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:26:31

US3192486

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:43:12

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered 'No (N)'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:26:31

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered 'un UNK 2000'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:26:31

US3192486

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:43:12

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered '0'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:26:31

US3192486

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:43:12

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User entered 'Jan 2000'	System	29 Aug 2020 23:26:31

US3192486
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 15:43:12
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User entered '2000'	System	29 Aug 2020 23:26:31

US3192486

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:43:12

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User entered 'Jan 2000'	System	29 Aug 2020 23:26:31

US3192486

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:43:12

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User entered '2000'	System	29 Aug 2020 23:26:31

US3192486

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:43:12

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Large intestine therapeutic procedures, PT: Appendicectomy, LLT: Appendectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Aug 2020 23:28:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Aug 2020 23:28:39
Data point term sent to Coder	System	29 Aug 2020 23:27:53
User entered 'Appendectomy'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:26:56

US3192486

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:43:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered 'un UNK 1980'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:26:56

US3192486

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:43:12

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered '0'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:26:56

US3192486

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:43:12

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered 'No (N)'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:26:56

US3192486

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered 'un UNK 1980'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:26:56

US3192486

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:43:12

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered '0'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:26:56

US3192486

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:43:12

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User entered 'Jan 1980'	System	29 Aug 2020 23:26:56

US3192486

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:43:12

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User entered '1980'	System	29 Aug 2020 23:26:56

US3192486

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:43:12

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User entered 'Jan 1980'	System	29 Aug 2020 23:26:56

US3192486

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:43:12

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User entered '1980'	System	29 Aug 2020 23:26:56

US3192486
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 15:43:12
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 17:07:37
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Arthroscopic surgery, LLT: Arthroscopic surgery - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Sep 2020 23:19:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Sep 2020 23:19:38
Data point term sent to Coder	System	18 Sep 2020 23:19:26
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' answered with 'UPDATED ' (Site from DM).	Norma Barrientos (b) (4) (b) (4)	18 Sep 2020 23:18:39
Coding entries removed.	Norma Barrientos (b) (4) (b) (4)	18 Sep 2020 23:18:30
User entered 'RIGHT KNEE ARTHROSCOPIC SURGERY' reason for change: Data Entry Error	Norma Barrientos (b) (4) (b) (4)	18 Sep 2020 23:18:30
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 14:22:24
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Knee operation, LLT: Knee operation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Aug 2020 23:28:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Aug 2020 23:28:39
Data point term sent to Coder	System	29 Aug 2020 23:27:55
User entered 'Right Knee Surgery'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:27:19

US3192486

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:43:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered 'un UNK 2010'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:27:19

US3192486

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:43:12

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered '0'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:27:19

US3192486

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:43:12

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered 'No (N)'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:27:19

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered 'un UNK 2010'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:27:19

US3192486

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:43:12

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered '0'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:27:19

US3192486

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:43:12

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User entered 'Jan 2010'	System	29 Aug 2020 23:27:19

US3192486

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:43:12

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User entered '2010'	System	29 Aug 2020 23:27:19

US3192486

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:43:12

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User entered 'Jan 2010'	System	29 Aug 2020 23:27:19

US3192486
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 15:43:12

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User entered '2010'	System	29 Aug 2020 23:27:19

US3192486

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:43:12

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 17:08:19
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Arthroscopic surgery, LLT: Arthroscopic surgery - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Sep 2020 23:19:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Sep 2020 23:19:38
Data point term sent to Coder	System	18 Sep 2020 23:19:26
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' answered with 'UPDATED ' (Site from DM).	Norma Barrientos (b) (4) (b) (4)	18 Sep 2020 23:19:02
Coding entries removed.	Norma Barrientos (b) (4) (b) (4)	18 Sep 2020 23:18:55
User entered 'LEFT KNEE ARTHROSCOPIC SURGERY' reason for change: Data Entry Error	Norma Barrientos (b) (4) (b) (4)	18 Sep 2020 23:18:55
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 14:22:00
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Knee operation, LLT: Knee operation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Aug 2020 23:28:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Aug 2020 23:28:39
Data point term sent to Coder	System	29 Aug 2020 23:27:55
User entered 'Left Knee Surgery'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:27:44

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Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:43:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered 'un UNK 2005'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:27:44

US3192486

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:43:12

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered '0'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:27:44

US3192486

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:43:12

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered 'No (N)'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:27:44

US3192486

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered 'un UNK 2005'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:27:44

US3192486

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:43:12

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered '0'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:27:44

US3192486

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:43:12

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User entered 'Jan 2005'	System	29 Aug 2020 23:27:44

US3192486

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:43:12

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User entered '2005'	System	29 Aug 2020 23:27:44

US3192486

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:43:12

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User entered 'Jan 2005'	System	29 Aug 2020 23:27:44

US3192486

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:43:12

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User entered '2005'	System	29 Aug 2020 23:27:44

US3192486

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:43:12

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type 2 diabetes mellitus - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Oct 2020 01:55:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Oct 2020 01:55:45
Data point term sent to Coder	System	01 Oct 2020 01:54:15
User entered 'DIABETES TYPE 2'	Crystal Mata (b) (4) (b) (4)	01 Oct 2020 01:53:23

US3192486

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:43:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:38:09
Signature has been broken.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:50:53
User entered 'un UNK 2018' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:50:53
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered empty.	Crystal Mata (b) (4) (b) (4)	01 Oct 2020 01:53:23

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US3192486
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 15:43:12
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:38:09
Signature has been broken.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:50:53
User entered '0' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:50:53
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered '1'	Crystal Mata (b) (4) (b) (4)	01 Oct 2020 01:53:23

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Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:43:12

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered 'Yes (Y)'	Crystal Mata (b) (4) (b) (4)	01 Oct 2020 01:53:23

US3192486

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered empty.	Crystal Mata (b) (4) (b) (4)	01 Oct 2020 01:53:23

US3192486

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:43:12

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered '0'	Crystal Mata (b) (4) (b) (4)	01 Oct 2020 01:53:23

US3192486

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:43:12

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User entered 'Jan 2018'	System	03 Apr 2021 17:50:53
User entered empty.	System	01 Oct 2020 01:53:23

US3192486

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:43:12

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User entered '2018'	System	03 Apr 2021 17:50:53
User entered empty.	System	01 Oct 2020 01:53:23

US3192486

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:43:12

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User entered empty.	System	01 Oct 2020 01:53:23

US3192486

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:43:12

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User entered empty.	System	01 Oct 2020 01:53:23

US3192486

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:43:12

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Pain, LLT: Chronic pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Oct 2020 01:56:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Oct 2020 01:56:37
Data point term sent to Coder	System	01 Oct 2020 01:55:16
User entered 'CHRONIC PAIN'	Crystal Mata (b) (4) (b) (4)	01 Oct 2020 01:55:05

US3192486

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:43:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:38:09
Signature has been broken.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:51:12
User entered 'un UNK 2010' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:51:12
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered empty.	Crystal Mata (b) (4) (b) (4)	01 Oct 2020 01:55:05

US3192486

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:43:12

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:38:09
Signature has been broken.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:51:12
User entered '0' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:51:12
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered '1'	Crystal Mata (b) (4) (b) (4)	01 Oct 2020 01:55:05

US3192486

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:43:12

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered 'Yes (Y)'	Crystal Mata (b) (4) (b) (4)	01 Oct 2020 01:55:05

US3192486

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered empty.	Crystal Mata (b) (4) (b) (4)	01 Oct 2020 01:55:05

US3192486

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:43:12

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered '0'	Crystal Mata (b) (4) (b) (4)	01 Oct 2020 01:55:05

US3192486

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:43:12

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User entered 'Jan 2010'	System	03 Apr 2021 17:51:12
User entered empty.	System	01 Oct 2020 01:55:05

US3192486

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:43:12

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User entered '2010'	System	03 Apr 2021 17:51:12
User entered empty.	System	01 Oct 2020 01:55:05

US3192486
Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 15:43:12
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User entered empty.	System	01 Oct 2020 01:55:05

US3192486

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:43:12

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User entered empty.	System	01 Oct 2020 01:55:05

US3192486

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:43:12

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:38:09
User coded data point as SOC: Gastrointestinal disorders, HLGT: Exocrine pancreas conditions, HLT: Acute and chronic pancreatitis, PT: Pancreatitis chronic, LLT: Chronic pancreatitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Apr 2021 07:15:17
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Apr 2021 07:15:17
Data point term sent to Coder	System	03 Apr 2021 17:52:12
User entered 'Chronic pancratitis'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:51:42

US3192486

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:43:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:38:09
User entered 'un UNK 2005'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:51:42

US3192486

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:43:12

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:38:09
User entered '0'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:51:42

US3192486

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:43:12

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:38:09
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:51:42

US3192486

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:38:09
User entered empty.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:51:42

US3192486

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:43:12

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:38:09
User entered '0'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:51:42

US3192486

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:43:12

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User entered 'Jan 2005'	System	03 Apr 2021 17:51:42

US3192486
Folder: Screening
Form: Medical History (10)
Generated On: 09 Jun 2021 15:43:12
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User entered '2005'	System	03 Apr 2021 17:51:42

US3192486
Folder: Screening
Form: Medical History (10)
Generated On: 09 Jun 2021 15:43:12
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User entered empty.	System	03 Apr 2021 17:51:42

US3192486
Folder: Screening
Form: Medical History (10)
Generated On: 09 Jun 2021 15:43:12
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User entered empty.	System	03 Apr 2021 17:51:42

US3192486

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:43:12

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:38:09
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Apr 2021 17:53:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Apr 2021 17:53:41
Data point term sent to Coder	System	03 Apr 2021 17:52:12
User entered 'Anxiety'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:51:54

US3192486

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:43:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:38:09
User entered 'un UNK 1975'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:51:54

US3192486

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:43:12

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:38:09
User entered '0'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:51:54

US3192486
Folder: Screening
Form: Medical History (11)
Generated On: 09 Jun 2021 15:43:12
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:38:09
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:51:54

US3192486

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:38:09
User entered empty.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:51:54

US3192486

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:43:12

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:38:09
User entered '0'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:51:54

US3192486

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:43:12

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User entered 'Jan 1975'	System	03 Apr 2021 17:51:54

US3192486
Folder: Screening
Form: Medical History (11)
Generated On: 09 Jun 2021 15:43:12
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User entered '1975'	System	03 Apr 2021 17:51:54

US3192486

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:43:12

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User entered empty.	System	03 Apr 2021 17:51:54

US3192486

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:43:12

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User entered empty.	System	03 Apr 2021 17:51:54

US3192486

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:43:12

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:38:09
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastrooesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Apr 2021 17:54:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Apr 2021 17:54:41
Data point term sent to Coder	System	03 Apr 2021 17:53:12
User entered 'Gastroesophageal reflux disease'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:52:53

US3192486

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:43:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:38:09
User entered 'un UNK 2018'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:52:53

US3192486

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:43:12

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:38:09
User entered '0'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:52:53

US3192486

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:43:12

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:38:09
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:52:53

US3192486

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:38:09
User entered empty.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:52:53

US3192486

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:43:12

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:38:09
User entered '0'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:52:53

US3192486

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:43:12

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User entered 'Jan 2018'	System	03 Apr 2021 17:52:53

US3192486

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:43:12

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User entered '2018'	System	03 Apr 2021 17:52:53

US3192486

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:43:12

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User entered empty.	System	03 Apr 2021 17:52:53

US3192486
Folder: Screening
Form: Medical History (12)
Generated On: 09 Jun 2021 15:43:12

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User entered empty.	System	03 Apr 2021 17:52:53

US3192486

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:43:12

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:38:09
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Peripheral neuropathies NEC, PT: Neuropathy peripheral, LLT: Peripheral neuropathy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Apr 2021 17:54:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Apr 2021 17:54:42
Data point term sent to Coder	System	03 Apr 2021 17:53:12
User entered 'peripheral neuropathy'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:53:08

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Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:43:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:38:09
User entered 'un UNK 2019'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:53:08

US3192486

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:43:12

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:38:09
User entered '0'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:53:08

US3192486

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:43:12

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:38:09
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:53:08

US3192486

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:38:09
User entered empty.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:53:08

US3192486

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:43:12

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:38:09
User entered '0'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:53:08

US3192486

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:43:12

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User entered 'Jan 2019'	System	03 Apr 2021 17:53:08

US3192486

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:43:12

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User entered '2019'	System	03 Apr 2021 17:53:08

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User entered empty.	System	03 Apr 2021 17:53:08

US3192486

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:43:12

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User entered empty.	System	03 Apr 2021 17:53:08

US3192486

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:43:12

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:38:09
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Anaemias nonhaemolytic and marrow depression, HLT: Anaemias NEC, PT: Anaemia, LLT: Anemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Apr 2021 17:55:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Apr 2021 17:55:38
Data point term sent to Coder	System	03 Apr 2021 17:54:13
User entered 'Anemia'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:53:22

US3192486

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:43:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:38:09
User entered 'un UNK 2019'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:53:22

US3192486

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:43:12

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:38:09
User entered '0'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:53:22

US3192486

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:43:12

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:38:09
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:53:22

US3192486

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:38:09
User entered empty.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:53:22

US3192486

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:43:12

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:38:09
User entered '0'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:53:22

US3192486

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:43:12

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User entered 'Jan 2019'	System	03 Apr 2021 17:53:22

US3192486

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:43:12

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User entered '2019'	System	03 Apr 2021 17:53:22

US3192486

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:43:12

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User entered empty.	System	03 Apr 2021 17:53:22

US3192486
Folder: Screening
Form: Medical History (14)
Generated On: 09 Jun 2021 15:43:12

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User entered empty.	System	03 Apr 2021 17:53:22

US3192486

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:43:12

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:38:09
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Stress disorders, PT: Post-traumatic stress disorder, LLT: Post-traumatic stress disorder - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Apr 2021 17:55:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Apr 2021 17:55:37
Data point term sent to Coder	System	03 Apr 2021 17:54:14
User entered 'Post traumatic stress disorder'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:53:55

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Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:43:12

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:38:09
User entered 'un UNK 1970'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:53:55

US3192486

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:43:12

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:38:09
User entered '0'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:53:55

US3192486

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:43:12

Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:38:09
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:53:55

US3192486

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:38:09
User entered empty.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:53:55

US3192486

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:43:12

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:38:09
User entered '0'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:53:55

US3192486

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:43:12

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User entered 'Jan 1970'	System	03 Apr 2021 17:53:55

US3192486

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:43:12

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User entered '1970'	System	03 Apr 2021 17:53:55

US3192486

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:43:12

Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User entered empty.	System	03 Apr 2021 17:53:55

US3192486

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:43:12

Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User entered empty.	System	03 Apr 2021 17:53:55

US3192486
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:43:12
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered 'Yes (Y)'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:11:41

US3192486

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:12

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered '26 Aug 2020'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:11:41

US3192486

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered '08:20'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:11:41

US3192486

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:12

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User entered '26 Aug 2020 08:20'	System	29 Aug 2020 23:11:41

US3192486
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:43:12

Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered '71' in	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:11:41
DataPoint set to visible.	System	26 Aug 2020 16:07:42

US3192486
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:43:12

Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered '225' lb	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:11:41
DataPoint set to visible.	System	26 Aug 2020 16:07:42

US3192486

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:12

BMI *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User entered '31.44675'	System	29 Aug 2020 23:11:41
DataPoint set to visible.	System	26 Aug 2020 16:07:42

US3192486
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:43:12
BMI units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User entered 'kg/m2'	System	29 Aug 2020 23:11:41
DataPoint set to visible.	System	26 Aug 2020 16:07:42

US3192486

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:12

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered missing code ND - Not Done.	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:11:41

US3192486

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:12

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered empty.	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:11:41

US3192486
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:43:12
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered empty.	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:11:41

US3192486
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:43:12
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered missing code ND - Not Done.	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:11:41

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User entered 'bpm'	System	29 Aug 2020 23:11:41

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered missing code ND - Not Done.	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:11:41

FDA-CBER-2022-1614-0414842

US3192486
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:43:12
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User entered 'breaths/min'	System	29 Aug 2020 23:11:41

US3192486
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:43:12

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered missing code ND - Not Done.	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:11:41

US3192486
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:43:12

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User entered 'mmHg'	System	29 Aug 2020 23:11:41

US3192486

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:12

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered missing code ND - Not Done.	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:11:41

US3192486
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:43:12
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User entered 'mmHg'	System	29 Aug 2020 23:11:41

US3192486
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:43:12

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36

US3192486
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:43:12
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36

US3192486

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:43:12

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered 'Yes (Y)'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:12:13

US3192486

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:43:12

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered '26 Aug 2020'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:12:13

US3192486

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:43:12

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered 'No (N)'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:13:12

US3192486

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:43:12

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered 'No (N)'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:13:12

US3192486

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:43:12

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)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered 'No (N)'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:13:12

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)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered 'No (N)'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:13:12

FDA-CBER-2022-1614-0414855

US3192486

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:43:12

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered 'No (N)'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:13:12

US3192486

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:43:12

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)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered 'No (N)'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:13:12

US3192486

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:43:12

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)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered 'No (N)'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:13:12

US3192486

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:43:12

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)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered 'No (N)'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:13:12

US3192486

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:43:12

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)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered 'No (N)'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:13:12

US3192486

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:43:12

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)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered 'No (N)'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:13:12

US3192486

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:43:12

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)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered 'No (N)'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:13:12

US3192486

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:43:12

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered 'No (N)'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:13:12

US3192486

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:43:12

Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered empty.	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:13:12

US3192486

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:43:12

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered '0'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:13:12

US3192486

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:43:12

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered '0'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:13:12

US3192486

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:43:12

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)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered '0'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:13:12

US3192486

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:43:12

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)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered '0'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:13:12

US3192486

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:43:12

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)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered '0'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:13:12

US3192486

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered '1'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:13:12

US3192486
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:43:12
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered '0'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:13:12

US3192486
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:43:12
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered empty.	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:13:12

US3192486

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:43:12

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered 'Yes (Y)'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:15:55

US3192486

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:43:12

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered '26 Aug 2020'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:15:55

US3192486
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 15:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered 'Clinic (Clinic)'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:15:55

US3192486

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:43:12

Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User entered 'VISIT1'	System	29 Aug 2020 23:15:55

US3192486

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered '26 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 15:54:53

US3192486

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:43:12

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered '188318'	RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 15:54:53

US3192486

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:43:12

In what Cohort was the participant enrolled?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 15:54:53

US3192486

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:43:12

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)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered 'No (N)'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:06:42

US3192486

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:43:12

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)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered 'No (N)'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:06:42

US3192486

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered 'No (N)'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:06:42

US3192486

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:43:12

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered 'Yes (Y)'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:06:42

US3192486

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:43:12

Liver Disease

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered 'No (N)'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:06:42

US3192486

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:43:12

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered 'No (N)'	maggie Tono (b) (4) (b) (4)	22 Sep 2020 01:26:21
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 09:46:52
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:02:30

Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 15:43:12

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered missing code ND - Not Done.	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:18:37

US3192486

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:43:12

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered missing code ND - Not Done.	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:18:37

US3192486
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 15:43:12
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered missing code ND - Not Done.	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:18:37

US3192486
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 15:43:12
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered missing code ND - Not Done.	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:18:37

US3192486

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:12

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User accepted default value 'Pre-Dose (PREDOSE)'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:18:37

US3192486

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:12

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered 'Yes (Y)'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:18:37

US3192486

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:12

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered '26 Aug 2020'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:18:37

US3192486

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered '08:20'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:18:37

US3192486

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:12

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User entered '26 Aug 2020 08:20'	System	29 Aug 2020 23:18:37

US3192486

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:12

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered '98.7' F	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:18:37

US3192486

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:12

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered 'Oral (Oral)'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:18:37

US3192486
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:43:12
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered empty.	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:18:37

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered '60'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:18:37

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:12

Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User entered 'bpm'	System	29 Aug 2020 23:18:37

US3192486

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:12

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered '17'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:18:37

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User entered 'breaths/min'	System	29 Aug 2020 23:18:37

US3192486

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:12

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered '118'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:18:37

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User entered 'mmHg'	System	29 Aug 2020 23:18:37

US3192486

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:12

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered '70'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:18:37

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:12

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User entered 'mmHg'	System	29 Aug 2020 23:18:37

US3192486

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:43:12

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered missing code ND - Not Done.	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:18:37

FDA-CBER-2022-1614-0414906

US3192486
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 15:43:12
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered missing code ND - Not Done.	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:18:37

US3192486

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:12

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User accepted default value 'Post-Dose (POSTDOSE)'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:18:37

US3192486

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:12

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered 'Yes (Y)'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:18:37

US3192486

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:12

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered '26 Aug 2020'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:18:37

US3192486

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered '10:21'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:18:37

US3192486

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:12

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User entered '26 Aug 2020 10:21'	System	29 Aug 2020 23:18:37

US3192486

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:12

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered '97.8' F	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:18:37

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:12

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered 'Oral (Oral)'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:18:37

US3192486
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:43:12
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered empty.	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:18:37

US3192486

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:12

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered '58'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:18:37

US3192486
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:43:12
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User entered 'bpm'	System	29 Aug 2020 23:18:37

US3192486

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:12

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered '14'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:18:37

FDA-CBER-2022-1614-0414918

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:12

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User entered 'breaths/min'	System	29 Aug 2020 23:18:37

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered '137'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:18:37

FDA-CBER-2022-1614-0414920

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User entered 'mmHg'	System	29 Aug 2020 23:18:37

US3192486

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:12

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered '83'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:18:37

US3192486
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:43:12
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User entered 'mmHg'	System	29 Aug 2020 23:18:37

US3192486
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 09 Jun 2021 15:43:12
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered 'No (N)'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:15:34

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:43:12

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered empty.	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:15:34

US3192486
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 15:43:12
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered 'Yes (Y)'	Tianna Young (b) (4) (b) (4)	26 Aug 2020 16:08:28

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US3192486
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 15:43:12
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered empty.	Tianna Young (b) (4) (b) (4)	26 Aug 2020 16:08:28

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Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 15:43:12

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)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered empty.	Tianna Young (b) (4) (b) (4)	26 Aug 2020 16:08:28

Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 15:43:12
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User entered 'MRNA-1273 OR PLACEBO'	System	26 Aug 2020 16:08:28

FDA-CBER-2022-1614-0414929

Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 15:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered '26 Aug 2020'	Tianna Young (b) (4) (b) (4)	26 Aug 2020 16:08:28

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered '08:58'	Tianna Young (b) (4) (b) (4)	26 Aug 2020 16:08:28

US3192486

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:43:12

Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User entered '26 Aug 2020 08:58'	System	26 Aug 2020 16:08:28

US3192486
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 15:43:12
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered 'Left Arm (LEFT ARM)'	Tianna Young (b) (4) (b) (4)	26 Aug 2020 16:08:28

US3192486
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 15:43:12
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User entered 'ONCE'	System	26 Aug 2020 16:08:28

FDA-CBER-2022-1614-0414934

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Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 15:43:12
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User entered 'INTRAMUSCULAR'	System	26 Aug 2020 16:08:28

US3192486

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:43:12

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered 'Yes (Y)'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:14:38

US3192486

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:43:12

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered '26 Aug 2020'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:14:38

US3192486

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered '08:44'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:14:38

US3192486

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:43:12

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User entered '26 Aug 2020 08:44'	System	29 Aug 2020 23:14:38

US3192486

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:43:12

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered '26 Aug 2020'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:14:18

US3192486

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:43:12

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:14:18

US3192486

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:43:12

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered 'Yes (Y)'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:14:18

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered '08:46'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:14:18

US3192486

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:43:12

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User entered '26 Aug 2020 08:46'	System	29 Aug 2020 23:14:18

US3192486

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:43:12

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:14:18

Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 15:43:12
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered 'No (N)'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:14:18

US3192486

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered empty.	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:14:18

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User entered empty.	System	29 Aug 2020 23:14:18

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US3192486

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:43:12

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered 'Yes (Y)'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:13:52

US3192486
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 09 Jun 2021 15:43:12
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User entered '1'	System	29 Aug 2020 23:13:52

US3192486
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
Data entry locked.	System	26 Aug 2020 16:08:28
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 16:08:28

US3192486

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:43:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-08-26T09:24:14', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '4802e305-ba42-46f0-9996-d06a2f19de65'	System	26 Aug 2020 16:28:52
User entered 'Yes (Y)'	System	26 Aug 2020 16:28:52

US3192486

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:43:12

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-08-26T09:28:27', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '4802e305-ba42-46f0-9996-d06a2f19de65'	System	26 Aug 2020 16:28:52
User entered '97.8'	System	26 Aug 2020 16:28:52

US3192486

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-08-26T09:28:35', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '4802e305-ba42-46f0-9996-d06a2f19de65'	System	26 Aug 2020 16:28:52
User entered 'No (N)'	System	26 Aug 2020 16:28:52

US3192486

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:43:12

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-08-26T09:28:45', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '4802e305-ba42-46f0-9996-d06a2f19de65'	System	26 Aug 2020 16:28:52
User entered '26 Aug 2020 09:28'	System	26 Aug 2020 16:28:52

US3192486

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:43:12

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
User entered '26 Aug 2020 09:18'	System	26 Aug 2020 16:08:28

US3192486

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:43:12

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
User entered '26 Aug 2020 11:48'	System	26 Aug 2020 16:08:28

US3192486

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:43:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
Data entry locked.	System	26 Aug 2020 16:08:28
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 16:08:28

US3192486

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:43:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-08-27T09:39:43', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '173fc186-d85c-4167-9c47-64b7f540353c'	System	27 Aug 2020 16:40:16
User entered 'Yes (Y)'	System	27 Aug 2020 16:40:16

US3192486

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:43:12

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-08-27T09:39:54', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '173fc186-d85c-4167-9c47-64b7f540353c'	System	27 Aug 2020 16:40:16
User entered '97.8'	System	27 Aug 2020 16:40:16

US3192486

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-08-27T09:40:01', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '173fc186-d85c-4167-9c47-64b7f540353c'	System	27 Aug 2020 16:40:16
User entered 'No (N)'	System	27 Aug 2020 16:40:16

US3192486

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:43:12

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-08-27T09:40:12', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '173fc186-d85c-4167-9c47-64b7f540353c'	System	27 Aug 2020 16:40:16
User entered '27 Aug 2020 09:40'	System	27 Aug 2020 16:40:16

US3192486
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:43:12
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
User entered '26 Aug 2020 12:43'	System	26 Aug 2020 16:08:28

US3192486

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:43:12

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 16:08:28

US3192486
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
Data entry locked.	System	26 Aug 2020 16:08:28
User entered 'Day 2'	System	26 Aug 2020 16:08:28

US3192486
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:43:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-08-28T06:04:46', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '9d039cbe-4a1a-4d75-aec6-a874ccdb7308'	System	28 Aug 2020 13:05:17
User entered 'Yes (Y)'	System	28 Aug 2020 13:05:17

US3192486

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:43:12

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-08-28T06:04:55', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '9d039cbe-4a1a-4d75-aec6-a874ccdb7308'	System	28 Aug 2020 13:05:17
User entered '97.8'	System	28 Aug 2020 13:05:17

US3192486

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-08-28T06:05:04', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '9d039cbe-4a1a-4d75-aec6-a874ccdb7308'	System	28 Aug 2020 13:05:17
User entered 'No (N)'	System	28 Aug 2020 13:05:17

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US3192486
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:43:12

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-08-28T06:05:12', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '9d039cbe-4a1a-4d75-aec6-a874ccdb7308'	System	28 Aug 2020 13:05:17
User entered '28 Aug 2020 06:05'	System	28 Aug 2020 13:05:17

US3192486
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:43:12
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 16:08:28

US3192486
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:43:12

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 16:08:28

US3192486

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:43:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
Data entry locked.	System	26 Aug 2020 16:08:28
User entered 'Day 3'	System	26 Aug 2020 16:08:28

US3192486
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:43:12
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30

US3192486
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:43:12

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30

US3192486

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30

US3192486

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:43:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30

US3192486
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:43:12
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30

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US3192486
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:43:12
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30

US3192486
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:43:12

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 16:08:28

US3192486
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:43:12
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 16:08:28

US3192486
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
Data entry locked.	System	26 Aug 2020 16:08:28
User entered 'Day 4'	System	26 Aug 2020 16:08:28

US3192486

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:43:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-08-29T14:49:00', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '61bf74a4-a688-4e04-bf4b-2e7cda65a5bc'	System	29 Aug 2020 21:49:20
User entered 'Yes (Y)'	System	29 Aug 2020 21:49:20

US3192486
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:43:12

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-08-29T14:49:09', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '61bf74a4-a688-4e04-bf4b-2e7cda65a5bc'	System	29 Aug 2020 21:49:20
User entered '97.6'	System	29 Aug 2020 21:49:20

US3192486

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-08-29T14:49:13', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '61bf74a4-a688-4e04-bf4b-2e7cda65a5bc'	System	29 Aug 2020 21:49:20
User entered 'No (N)'	System	29 Aug 2020 21:49:20

US3192486
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:43:12
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-08-29T14:49:19', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '61bf74a4-a688-4e04-bf4b-2e7cda65a5bc'	System	29 Aug 2020 21:49:20
User entered '29 Aug 2020 14:49'	System	29 Aug 2020 21:49:20

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 16:08:28

US3192486

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:43:12

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 16:08:28

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US3192486
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
Data entry locked.	System	26 Aug 2020 16:08:28
User entered 'Day 5'	System	26 Aug 2020 16:08:28

US3192486

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:43:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-08-31T05:59:26', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '4680ad6d-11f3-470c-a8d9-30d57d0dd799'	System	31 Aug 2020 12:59:55
User entered 'Yes (Y)'	System	31 Aug 2020 12:59:55

US3192486
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:43:12

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-08-31T05:59:39', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '4680ad6d-11f3-470c-a8d9-30d57d0dd799'	System	31 Aug 2020 12:59:55
User entered '97.5'	System	31 Aug 2020 12:59:55

US3192486

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-08-31T05:59:47', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '4680ad6d-11f3-470c-a8d9-30d57d0dd799'	System	31 Aug 2020 12:59:55
User entered 'No (N)'	System	31 Aug 2020 12:59:55

US3192486

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:43:12

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-08-31T05:59:53', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '4680ad6d-11f3-470c-a8d9-30d57d0dd799'	System	31 Aug 2020 12:59:55
User entered '31 Aug 2020 05:59'	System	31 Aug 2020 12:59:55

US3192486

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:43:12

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 16:08:28

US3192486

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:43:12

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 16:08:28

US3192486
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
Data entry locked.	System	26 Aug 2020 16:08:28
User entered 'Day 6'	System	26 Aug 2020 16:08:28

US3192486
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:43:12
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30

US3192486
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:43:12

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30

US3192486
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:43:12
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30

FDA-CBER-2022-1614-0414998

US3192486

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:43:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30

US3192486
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:43:12

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30

FDA-CBER-2022-1614-0415000

US3192486

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:43:12

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30

US3192486
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:43:12

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 16:08:28

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 16:08:28

US3192486
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
Data entry locked.	System	26 Aug 2020 16:08:28
User entered 'Day 7'	System	26 Aug 2020 16:08:28

US3192486

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:43:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-01T12:01:06', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '011f07cb-7d2c-4c80-a770-4443abc0a4ca'	System	01 Sep 2020 19:01:25
User entered 'Yes (Y)'	System	01 Sep 2020 19:01:25

US3192486

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:43:12

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-01T12:01:13', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '011f07cb-7d2c-4c80-a770-4443abc0a4ca'	System	01 Sep 2020 19:01:25
User entered '97.8'	System	01 Sep 2020 19:01:25

US3192486

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-01T12:01:18', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '011f07cb-7d2c-4c80-a770-4443abc0a4ca'	System	01 Sep 2020 19:01:25
User entered 'No (N)'	System	01 Sep 2020 19:01:25

FDA-CBER-2022-1614-0415007

US3192486

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:43:12

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-01T12:01:21', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '011f07cb-7d2c-4c80-a770-4443abc0a4ca'	System	01 Sep 2020 19:01:25
User entered '01 Sep 2020 12:01'	System	01 Sep 2020 19:01:25

US3192486

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:43:12

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 16:08:28

US3192486

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:43:12

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 16:08:28

US3192486
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
Data entry locked.	System	26 Aug 2020 16:08:28
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 16:08:28

US3192486

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:43:12

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-08-26T09:28:55', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '4586cf8a-3c77-4a6c-bded-71e5ae45bfd3'	System	26 Aug 2020 16:29:18
User entered 'None (1)'	System	26 Aug 2020 16:29:18

US3192486

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:43:12

Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-08-26T09:29:00', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '4586cf8a-3c77-4a6c-bded-71e5ae45bfd3'	System	26 Aug 2020 16:29:18
User entered 'No (N)'	System	26 Aug 2020 16:29:18

US3192486

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:43:12

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-08-26T09:29:05', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '4586cf8a-3c77-4a6c-bded-71e5ae45bfd3'	System	26 Aug 2020 16:29:18
User entered 'No (N)'	System	26 Aug 2020 16:29:18

US3192486

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:43:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-08-26T09:29:10', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '4586cf8a-3c77-4a6c-bded-71e5ae45bfd3'	System	26 Aug 2020 16:29:18
User entered 'None (1)'	System	26 Aug 2020 16:29:18

US3192486
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:43:12
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-08-26T09:29:15', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '4586cf8a-3c77-4a6c-bded-71e5ae45bfd3'	System	26 Aug 2020 16:29:18
User entered '26 Aug 2020 09:29'	System	26 Aug 2020 16:29:18

US3192486

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:43:12

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
User entered '26 Aug 2020 09:18'	System	26 Aug 2020 16:08:28

US3192486

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:43:12

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
User entered '26 Aug 2020 11:48'	System	26 Aug 2020 16:08:28

US3192486
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
Data entry locked.	System	26 Aug 2020 16:08:28
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 16:08:28

US3192486
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:43:12

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-08-27T09:40:22', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: 'f1d4e469-c017-4b8d-b166-4adfd9f25f3d'	System	27 Aug 2020 16:40:59
User entered 'None (1)'	System	27 Aug 2020 16:40:59

US3192486
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:43:12
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-08-27T09:40:26', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: 'f1d4e469-c017-4b8d-b166-4adfd9f25f3d'	System	27 Aug 2020 16:40:59
User entered 'No (N)'	System	27 Aug 2020 16:40:59

US3192486

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:43:12

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-08-27T09:40:30', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: 'f1d4e469-c017-4b8d-b166-4adfd9f25f3d'	System	27 Aug 2020 16:40:59
User entered 'No (N)'	System	27 Aug 2020 16:40:59

US3192486

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:43:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-08-27T09:40:35', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: 'f1d4e469-c017-4b8d-b166-4adfd9f25f3d'	System	27 Aug 2020 16:40:59
User entered 'None (1)'	System	27 Aug 2020 16:40:59

US3192486

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:43:12

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-08-27T09:40:42', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: 'f1d4e469-c017-4b8d-b166-4adfd9f25f3d'	System	27 Aug 2020 16:40:59
User entered '27 Aug 2020 09:40'	System	27 Aug 2020 16:40:59

US3192486

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:43:12

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
User entered '26 Aug 2020 12:43'	System	26 Aug 2020 16:08:28

US3192486

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:43:12

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 16:08:28

US3192486
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
Data entry locked.	System	26 Aug 2020 16:08:28
User entered 'Day 2'	System	26 Aug 2020 16:08:28

US3192486

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:43:12

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-08-28T06:05:26', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: 'f0c3ac16-3cc9-47bc-9278-cc1a9d66cf07'	System	28 Aug 2020 13:05:54
User entered 'None (1)'	System	28 Aug 2020 13:05:54

US3192486

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:43:12

Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-08-28T06:05:30', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: 'f0c3ac16-3cc9-47bc-9278-cc1a9d66cf07'	System	28 Aug 2020 13:05:54
User entered 'No (N)'	System	28 Aug 2020 13:05:54

US3192486

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:43:12

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-08-28T06:05:35', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: 'f0c3ac16-3cc9-47bc-9278-cc1a9d66cf07'	System	28 Aug 2020 13:05:54
User entered 'No (N)'	System	28 Aug 2020 13:05:54

US3192486

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:43:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-08-28T06:05:47', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: 'f0c3ac16-3cc9-47bc-9278-cc1a9d66cf07'	System	28 Aug 2020 13:05:54
User entered 'None (1)'	System	28 Aug 2020 13:05:54

US3192486
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:43:12
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-08-28T06:05:52', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: 'f0c3ac16-3cc9-47bc-9278-cc1a9d66cf07'	System	28 Aug 2020 13:05:54
User entered '28 Aug 2020 06:05'	System	28 Aug 2020 13:05:54

US3192486
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:43:12

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 16:08:28

US3192486
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:43:12
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 16:08:28

US3192486
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
Data entry locked.	System	26 Aug 2020 16:08:28
User entered 'Day 3'	System	26 Aug 2020 16:08:28

US3192486

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:43:12

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30

US3192486
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:43:12

Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30

US3192486
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:43:12
Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30

US3192486

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:43:12

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30

US3192486

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:43:12

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)	25 Feb 2021 18:58:30

US3192486

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:43:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30

US3192486
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:43:12
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30

US3192486
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:43:12
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 16:08:28

US3192486

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:43:12

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 16:08:28

US3192486
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
Data entry locked.	System	26 Aug 2020 16:08:28
User entered 'Day 4'	System	26 Aug 2020 16:08:28

US3192486

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:43:12

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-08-29T14:49:25', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '1a985d1d-3948-4f20-a6f1-5f70cee36f51'	System	29 Aug 2020 21:49:44
User entered 'None (1)'	System	29 Aug 2020 21:49:44

US3192486
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:43:12

Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-08-29T14:49:29', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '1a985d1d-3948-4f20-a6f1-5f70cee36f51'	System	29 Aug 2020 21:49:44
User entered 'No (N)'	System	29 Aug 2020 21:49:44

US3192486

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:43:12

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-08-29T14:49:32', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '1a985d1d-3948-4f20-a6f1-5f70cee36f51'	System	29 Aug 2020 21:49:44
User entered 'No (N)'	System	29 Aug 2020 21:49:44

US3192486

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:43:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-08-29T14:49:37', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '1a985d1d-3948-4f20-a6f1-5f70cee36f51'	System	29 Aug 2020 21:49:44
User entered 'None (1)'	System	29 Aug 2020 21:49:44

US3192486

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:43:12

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-08-29T14:49:41', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '1a985d1d-3948-4f20-a6f1-5f70cee36f51'	System	29 Aug 2020 21:49:44
User entered '29 Aug 2020 14:49'	System	29 Aug 2020 21:49:44

US3192486

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:43:12

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 16:08:28

US3192486

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:43:12

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 16:08:28

US3192486
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
Data entry locked.	System	26 Aug 2020 16:08:28
User entered 'Day 5'	System	26 Aug 2020 16:08:28

US3192486

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:43:12

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-08-31T06:00:01', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '1b466d9b-ba7e-409c-95a5-59d87a5b0b0b'	System	31 Aug 2020 13:00:26
User entered 'None (1)'	System	31 Aug 2020 13:00:26

US3192486

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:43:12

Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-08-31T06:00:05', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '1b466d9b-ba7e-409c-95a5-59d87a5b0b0b'	System	31 Aug 2020 13:00:26
User entered 'No (N)'	System	31 Aug 2020 13:00:26

US3192486

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:43:12

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-08-31T06:00:10', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '1b466d9b-ba7e-409c-95a5-59d87a5b0b0b'	System	31 Aug 2020 13:00:26
User entered 'No (N)'	System	31 Aug 2020 13:00:26

US3192486

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:43:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-08-31T06:00:16', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '1b466d9b-ba7e-409c-95a5-59d87a5b0b0b'	System	31 Aug 2020 13:00:26
User entered 'None (1)'	System	31 Aug 2020 13:00:26

US3192486

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:43:12

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-08-31T06:00:19', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '1b466d9b-ba7e-409c-95a5-59d87a5b0b0b'	System	31 Aug 2020 13:00:26
User entered '31 Aug 2020 06:00'	System	31 Aug 2020 13:00:26

US3192486
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:43:12

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 16:08:28

US3192486

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:43:12

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 16:08:28

US3192486
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
Data entry locked.	System	26 Aug 2020 16:08:28
User entered 'Day 6'	System	26 Aug 2020 16:08:28

US3192486

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:43:12

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30

US3192486
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:43:12
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30

US3192486

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:43:12

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30

FDA-CBER-2022-1614-0415064

US3192486

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:43:12

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30

US3192486
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:43:12
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)	25 Feb 2021 18:58:30

US3192486

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:43:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30

US3192486
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:43:12
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30

US3192486
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:43:12

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 16:08:28

US3192486
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:43:12
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 16:08:28

US3192486
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
Data entry locked.	System	26 Aug 2020 16:08:28
User entered 'Day 7'	System	26 Aug 2020 16:08:28

US3192486

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:43:12

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-01T12:01:27', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '97e4d584-6c77-41f1-b9cc-c2122de5f58e'	System	01 Sep 2020 19:01:45
User entered 'None (1)'	System	01 Sep 2020 19:01:45

US3192486
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:43:12

Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-01T12:01:31', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '97e4d584-6c77-41f1-b9cc-c2122de5f58e'	System	01 Sep 2020 19:01:45
User entered 'No (N)'	System	01 Sep 2020 19:01:45

FDA-CBER-2022-1614-0415073

US3192486

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:43:12

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-01T12:01:35', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '97e4d584-6c77-41f1-b9cc-c2122de5f58e'	System	01 Sep 2020 19:01:45
User entered 'No (N)'	System	01 Sep 2020 19:01:45

US3192486

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:43:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-01T12:01:40', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '97e4d584-6c77-41f1-b9cc-c2122de5f58e'	System	01 Sep 2020 19:01:45
User entered 'None (1)'	System	01 Sep 2020 19:01:45

US3192486
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:43:12
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-01T12:01:43', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '97e4d584-6c77-41f1-b9cc-c2122de5f58e'	System	01 Sep 2020 19:01:45
User entered '01 Sep 2020 12:01'	System	01 Sep 2020 19:01:45

US3192486
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:43:12
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 16:08:28

US3192486

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:43:12

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 16:08:28

US3192486
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
Data entry locked.	System	26 Aug 2020 16:08:28
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 16:08:28

US3192486
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:43:12
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-08-26T09:29:21', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '6bf82d03-90db-4f1b-a0fd-94c9c8707f21'	System	26 Aug 2020 16:29:54
User entered 'None (0)'	System	26 Aug 2020 16:29:54

US3192486
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:43:12
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-08-26T09:29:25', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '6bf82d03-90db-4f1b-a0fd-94c9c8707f21'	System	26 Aug 2020 16:29:54
User entered 'None (0)'	System	26 Aug 2020 16:29:54

US3192486

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:43:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-08-26T09:29:29', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '6bf82d03-90db-4f1b-a0fd-94c9c8707f21'	System	26 Aug 2020 16:29:54
User entered 'None (0)'	System	26 Aug 2020 16:29:54

US3192486

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:43:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-08-26T09:29:33', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '6bf82d03-90db-4f1b-a0fd-94c9c8707f21'	System	26 Aug 2020 16:29:54
User entered 'None (0)'	System	26 Aug 2020 16:29:54

US3192486
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:43:12
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-08-26T09:29:36', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '6bf82d03-90db-4f1b-a0fd-94c9c8707f21'	System	26 Aug 2020 16:29:54
User entered 'None (0)'	System	26 Aug 2020 16:29:54

US3192486
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:43:12
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-08-26T09:29:39', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '6bf82d03-90db-4f1b-a0fd-94c9c8707f21'	System	26 Aug 2020 16:29:54
User entered 'None (0)'	System	26 Aug 2020 16:29:54

US3192486

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:43:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-08-26T09:29:42', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '6bf82d03-90db-4f1b-a0fd-94c9c8707f21'	System	26 Aug 2020 16:29:54
User entered 'No (N)'	System	26 Aug 2020 16:29:54

US3192486

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:43:12

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-08-26T09:29:45', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '6bf82d03-90db-4f1b-a0fd-94c9c8707f21'	System	26 Aug 2020 16:29:54
User entered '26 Aug 2020 09:29'	System	26 Aug 2020 16:29:54

US3192486

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:43:12

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
User entered '26 Aug 2020 09:18'	System	26 Aug 2020 16:08:28

US3192486

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:43:12

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
User entered '26 Aug 2020 11:48'	System	26 Aug 2020 16:08:28

US3192486
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
Data entry locked.	System	26 Aug 2020 16:08:28
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 16:08:28

US3192486
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:43:12
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-08-27T09:40:48', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '50680b8e-d53c-4fe1-9467-20561538877c'	System	27 Aug 2020 16:41:22
User entered 'None (0)'	System	27 Aug 2020 16:41:22

US3192486
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:43:12
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-08-27T09:40:52', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '50680b8e-d53c-4fe1-9467-20561538877c'	System	27 Aug 2020 16:41:22
User entered 'None (0)'	System	27 Aug 2020 16:41:22

US3192486

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:43:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-08-27T09:40:55', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '50680b8e-d53c-4fe1-9467-20561538877c'	System	27 Aug 2020 16:41:22
User entered 'None (0)'	System	27 Aug 2020 16:41:22

US3192486
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:43:12
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-08-27T09:40:58', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '50680b8e-d53c-4fe1-9467-20561538877c'	System	27 Aug 2020 16:41:22
User entered 'None (0)'	System	27 Aug 2020 16:41:22

US3192486
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:43:12
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-08-27T09:41:01', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '50680b8e-d53c-4fe1-9467-20561538877c'	System	27 Aug 2020 16:41:22
User entered 'None (0)'	System	27 Aug 2020 16:41:22

US3192486
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:43:12
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-08-27T09:41:03', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '50680b8e-d53c-4fe1-9467-20561538877c'	System	27 Aug 2020 16:41:22
User entered 'None (0)'	System	27 Aug 2020 16:41:22

US3192486

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:43:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-08-27T09:41:14', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '50680b8e-d53c-4fe1-9467-20561538877c'	System	27 Aug 2020 16:41:22
User entered 'No (N)'	System	27 Aug 2020 16:41:22

US3192486

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:43:12

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-08-27T09:41:19', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '50680b8e-d53c-4fe1-9467-20561538877c'	System	27 Aug 2020 16:41:22
User entered '27 Aug 2020 09:41'	System	27 Aug 2020 16:41:22

US3192486

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:43:12

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
User entered '26 Aug 2020 12:43'	System	26 Aug 2020 16:08:28

US3192486

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:43:12

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 16:08:28

US3192486
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
Data entry locked.	System	26 Aug 2020 16:08:28
User entered 'Day 2'	System	26 Aug 2020 16:08:28

US3192486
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:43:12
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-08-28T06:05:59', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '6c67b372-40f6-4537-b7db-016d0683ca15'	System	28 Aug 2020 13:06:34
User entered 'None (0)'	System	28 Aug 2020 13:06:34

US3192486
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:43:12
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-08-28T06:06:04', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '6c67b372-40f6-4537-b7db-016d0683ca15'	System	28 Aug 2020 13:06:34
User entered 'None (0)'	System	28 Aug 2020 13:06:34

US3192486

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:43:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-08-28T06:06:09', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '6c67b372-40f6-4537-b7db-016d0683ca15'	System	28 Aug 2020 13:06:34
User entered 'None (0)'	System	28 Aug 2020 13:06:34

US3192486

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:43:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-08-28T06:06:13', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '6c67b372-40f6-4537-b7db-016d0683ca15'	System	28 Aug 2020 13:06:34
User entered 'None (0)'	System	28 Aug 2020 13:06:34

US3192486
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:43:12
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-08-28T06:06:17', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '6c67b372-40f6-4537-b7db-016d0683ca15'	System	28 Aug 2020 13:06:34
User entered 'None (0)'	System	28 Aug 2020 13:06:34

US3192486
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:43:12
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-08-28T06:06:21', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '6c67b372-40f6-4537-b7db-016d0683ca15'	System	28 Aug 2020 13:06:34
User entered 'None (0)'	System	28 Aug 2020 13:06:34

US3192486
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:43:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-08-28T06:06:27', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '6c67b372-40f6-4537-b7db-016d0683ca15'	System	28 Aug 2020 13:06:34
User entered 'No (N)'	System	28 Aug 2020 13:06:34

US3192486

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:43:12

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-08-28T06:06:31', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '6c67b372-40f6-4537-b7db-016d0683ca15'	System	28 Aug 2020 13:06:34
User entered '28 Aug 2020 06:06'	System	28 Aug 2020 13:06:34

US3192486

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:43:12

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 16:08:28

US3192486
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:43:12
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 16:08:28

US3192486
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
Data entry locked.	System	26 Aug 2020 16:08:28
User entered 'Day 3'	System	26 Aug 2020 16:08:28

US3192486
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:43:12
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30

US3192486
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:43:12
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30

US3192486
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:43:12
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30

US3192486
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:43:12
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30

US3192486
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:43:12
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30

US3192486
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:43:12
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30

US3192486
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:43:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30

US3192486

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:43:12

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30

US3192486

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:43:12

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 16:08:28

US3192486
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:43:12
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 16:08:28

US3192486
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
Data entry locked.	System	26 Aug 2020 16:08:28
User entered 'Day 4'	System	26 Aug 2020 16:08:28

US3192486
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:43:12
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-08-29T14:49:47', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: 'bb597173-d96c-4b4b-93d4-1eb154dd17d2'	System	29 Aug 2020 21:50:12
User entered 'None (0)'	System	29 Aug 2020 21:50:12

US3192486
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:43:12
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-08-29T14:49:50', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: 'bb597173-d96c-4b4b-93d4-1eb154dd17d2'	System	29 Aug 2020 21:50:12
User entered 'None (0)'	System	29 Aug 2020 21:50:12

US3192486
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:43:12
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-08-29T14:49:53', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: 'bb597173-d96c-4b4b-93d4-1eb154dd17d2'	System	29 Aug 2020 21:50:12
User entered 'None (0)'	System	29 Aug 2020 21:50:12

US3192486
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:43:12
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-08-29T14:49:56', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: 'bb597173-d96c-4b4b-93d4-1eb154dd17d2'	System	29 Aug 2020 21:50:12
User entered 'None (0)'	System	29 Aug 2020 21:50:12

US3192486
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:43:12
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-08-29T14:49:59', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: 'bb597173-d96c-4b4b-93d4-1eb154dd17d2'	System	29 Aug 2020 21:50:12
User entered 'None (0)'	System	29 Aug 2020 21:50:12

US3192486

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:43:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-08-29T14:50:02', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: 'bb597173-d96c-4b4b-93d4-1eb154dd17d2'	System	29 Aug 2020 21:50:12
User entered 'None (0)'	System	29 Aug 2020 21:50:12

US3192486

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:43:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-08-29T14:50:07', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: 'bb597173-d96c-4b4b-93d4-1eb154dd17d2'	System	29 Aug 2020 21:50:12
User entered 'No (N)'	System	29 Aug 2020 21:50:12

US3192486

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:43:12

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-08-29T14:50:10', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: 'bb597173-d96c-4b4b-93d4-1eb154dd17d2'	System	29 Aug 2020 21:50:12
User entered '29 Aug 2020 14:50'	System	29 Aug 2020 21:50:12

US3192486

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:43:12

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 16:08:28

US3192486

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:43:12

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 16:08:28

US3192486
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
Data entry locked.	System	26 Aug 2020 16:08:28
User entered 'Day 5'	System	26 Aug 2020 16:08:28

US3192486
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:43:12
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-08-31T06:00:26', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: 'def7b6ce-3ec0-46f5-991a-a8a7d0391a39'	System	31 Aug 2020 13:01:00
User entered 'None (0)'	System	31 Aug 2020 13:01:00

US3192486
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:43:12
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-08-31T06:00:29', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: 'def7b6ce-3ec0-46f5-991a-a8a7d0391a39'	System	31 Aug 2020 13:01:00
User entered 'None (0)'	System	31 Aug 2020 13:01:00

US3192486
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:43:12
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-08-31T06:00:33', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: 'def7b6ce-3ec0-46f5-991a-a8a7d0391a39'	System	31 Aug 2020 13:01:00
User entered 'None (0)'	System	31 Aug 2020 13:01:00

US3192486

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:43:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-08-31T06:00:38', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: 'def7b6ce-3ec0-46f5-991a-a8a7d0391a39'	System	31 Aug 2020 13:01:00
User entered 'None (0)'	System	31 Aug 2020 13:01:00

US3192486
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:43:12
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-08-31T06:00:42', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: 'def7b6ce-3ec0-46f5-991a-a8a7d0391a39'	System	31 Aug 2020 13:01:00
User entered 'None (0)'	System	31 Aug 2020 13:01:00

US3192486
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:43:12
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-08-31T06:00:45', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: 'def7b6ce-3ec0-46f5-991a-a8a7d0391a39'	System	31 Aug 2020 13:01:00
User entered 'None (0)'	System	31 Aug 2020 13:01:00

US3192486

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:43:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-08-31T06:00:52', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: 'def7b6ce-3ec0-46f5-991a-a8a7d0391a39'	System	31 Aug 2020 13:01:00
User entered 'No (N)'	System	31 Aug 2020 13:01:00

US3192486

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:43:12

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-08-31T06:00:55', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: 'def7b6ce-3ec0-46f5-991a-a8a7d0391a39'	System	31 Aug 2020 13:01:00
User entered '31 Aug 2020 06:00'	System	31 Aug 2020 13:01:00

US3192486

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:43:12

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 16:08:28

US3192486

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:43:12

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 16:08:28

US3192486
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
Data entry locked.	System	26 Aug 2020 16:08:28
User entered 'Day 6'	System	26 Aug 2020 16:08:28

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30

US3192486
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:43:12
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30

US3192486
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:43:12
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30

US3192486
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:43:12
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30

US3192486
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:43:12
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30

US3192486

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:43:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30

US3192486

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:43:12

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30

US3192486

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:43:12

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 16:08:28

US3192486

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:43:12

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 16:08:28

US3192486

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:43:12

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
Data entry locked.	System	26 Aug 2020 16:08:28
User entered 'Day 7'	System	26 Aug 2020 16:08:28

US3192486
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:43:12
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-01T12:01:53', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '56fddb7f-baf4-4041-8c69-e50eb906202b'	System	01 Sep 2020 19:02:28
User entered 'None (0)'	System	01 Sep 2020 19:02:28

US3192486
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:43:12
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-01T12:02:04', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '56fddb7f-baf4-4041-8c69-e50eb906202b'	System	01 Sep 2020 19:02:28
User entered 'None (0)'	System	01 Sep 2020 19:02:28

US3192486
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:43:12
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-01T12:02:08', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '56fddb7f-baf4-4041-8c69-e50eb906202b'	System	01 Sep 2020 19:02:28
User entered 'None (0)'	System	01 Sep 2020 19:02:28

US3192486

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:43:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-01T12:02:11', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '56fddb7f-baf4-4041-8c69-e50eb906202b'	System	01 Sep 2020 19:02:28
User entered 'None (0)'	System	01 Sep 2020 19:02:28

US3192486
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:43:12
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-01T12:02:15', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '56fddb7f-baf4-4041-8c69-e50eb906202b'	System	01 Sep 2020 19:02:28
User entered 'None (0)'	System	01 Sep 2020 19:02:28

US3192486
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:43:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-01T12:02:18', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '56fddb7f-baf4-4041-8c69-e50eb906202b'	System	01 Sep 2020 19:02:28
User entered 'None (0)'	System	01 Sep 2020 19:02:28

US3192486
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:43:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-01T12:02:22', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '56fddb7f-baf4-4041-8c69-e50eb906202b'	System	01 Sep 2020 19:02:28
User entered 'No (N)'	System	01 Sep 2020 19:02:28

US3192486

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:43:12

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-01T12:02:25', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '56fddb7f-baf4-4041-8c69-e50eb906202b'	System	01 Sep 2020 19:02:28
User entered '01 Sep 2020 12:02'	System	01 Sep 2020 19:02:28

US3192486

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:43:12

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 16:08:28

US3192486
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:43:12
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 16:08:28

US3192486
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:43:12

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	12 Sep 2020 15:57:38

US3192486

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:12

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered '05 Sep 2020'	Yvonne De Los Reyes (b) (4)	12 Sep 2020 15:57:38

US3192486
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:43:12
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered 'Contact Made (CONTACT MADE)'	Yvonne De Los Reyes (b) (4)	12 Sep 2020 15:57:38

US3192486

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:12

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered empty.	Yvonne De Los Reyes (b) (4)	12 Sep 2020 15:57:38

US3192486

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:43:12

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	12 Sep 2020 15:57:46

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User entered '1'	System	12 Sep 2020 15:57:46

US3192486

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:12

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:58:07
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	12 Sep 2020 15:58:10

US3192486

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:12

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:58:07
User entered '09 Sep 2020'	Yvonne De Los Reyes (b) (4)	12 Sep 2020 15:58:10

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:58:07
User entered 'Contact Made (CONTACT MADE)'	Yvonne De Los Reyes (b) (4)	12 Sep 2020 15:58:10

FDA-CBER-2022-1614-0415175

US3192486
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:43:12
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:58:07
User entered empty.	Yvonne De Los Reyes (b) (4)	12 Sep 2020 15:58:10

US3192486

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:43:12

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:58:07
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	12 Sep 2020 15:58:16

US3192486
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:43:12
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User entered '1'	System	12 Sep 2020 15:58:16

US3192486
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:43:12

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered 'Yes (Y)'	Norma Barrientos (b) (4) (b) (4)	19 Sep 2020 18:40:03

US3192486

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:12

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered '19 Sep 2020'	Norma Barrientos (b) (4) (b) (4)	19 Sep 2020 18:40:03

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered 'Contact Made (CONTACT MADE)'	Norma Barrientos (b) (4) (b) (4)	19 Sep 2020 18:40:03

US3192486
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:43:12
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered empty.	Norma Barrientos (b) (4) (b) (4)	19 Sep 2020 18:40:03

US3192486
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:43:12

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered 'Yes (Y)'	Norma Barrientos (b) (4) (b) (4)	19 Sep 2020 18:40:16

US3192486

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:43:12

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User entered '1'	System	19 Sep 2020 18:40:16

US3192486

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:43:12

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 23OCT2020 is reported under Visit 3 Day 57visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 07:23:11
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 23OCT2020 is reported under Visit 3 Day 57visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with 'DATA FOR VISIT 3 HAS BEEN ENTERED AND COMPLETED. PLEASE REVISE. THANK YOU.' (Site from DM).	Crystal Mata (b) (4) (b) (4)	11 Nov 2020 01:46:11
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 23OCT2020 is reported under Visit 3 Day 57visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 06:43:18
User entered 'Yes (Y)'	Tianna Young (b) (4) (b) (4)	23 Sep 2020 17:16:18

US3192486

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:43:12

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered '23 Sep 2020'	Tianna Young (b) (4) (b) (4)	23 Sep 2020 17:16:18

US3192486

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered 'Clinic (Clinic)'	Tianna Young (b) (4) (b) (4)	23 Sep 2020 17:16:18

US3192486
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:43:12
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User entered 'VISIT2'	System	23 Sep 2020 17:16:18

US3192486

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:12

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User accepted default value 'Pre-Dose (PREDOSE)'	Tianna Young (b) (4) (b) (4)	23 Sep 2020 17:15:15

US3192486

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:12

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered 'Yes (Y)'	Tianna Young (b) (4) (b) (4)	23 Sep 2020 17:15:15

US3192486

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:12

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered '23 Sep 2020'	Tianna Young (b) (4) (b) (4)	23 Sep 2020 17:15:15

US3192486

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered '09:50'	Tianna Young (b) (4) (b) (4)	23 Sep 2020 17:15:15

US3192486

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:12

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User entered '23 Sep 2020 09:50'	System	23 Sep 2020 17:15:15

US3192486

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:12

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered '96.8' F	Tianna Young (b) (4) (b) (4)	23 Sep 2020 17:15:15

US3192486

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:12

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered 'Oral (Oral)'	Tianna Young (b) (4) (b) (4)	23 Sep 2020 17:15:15

US3192486

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:12

If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered empty.	Tianna Young (b) (4) (b) (4)	23 Sep 2020 17:15:15

US3192486

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:12

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered '52'	Tianna Young (b) (4) (b) (4)	23 Sep 2020 17:15:15

US3192486
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:43:12
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User entered 'bpm'	System	23 Sep 2020 17:15:15

US3192486

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:12

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered '12'	Tianna Young (b) (4) (b) (4)	23 Sep 2020 17:15:15

US3192486
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:43:12
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User entered 'breaths/min'	System	23 Sep 2020 17:15:15

US3192486

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:12

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered '142'	Tianna Young (b) (4) (b) (4)	23 Sep 2020 17:15:15

US3192486

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:12

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User entered 'mmHg'	System	23 Sep 2020 17:15:15

US3192486

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:12

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered '87'	Tianna Young (b) (4) (b) (4)	23 Sep 2020 17:15:15

US3192486

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:12

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User entered 'mmHg'	System	23 Sep 2020 17:15:15

US3192486

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:12

Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User accepted default value 'Post-Dose (POSTDOSE)'	Amanda Hermosillo (b) (4)	23 Sep 2020 17:44:49

US3192486

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:12

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered 'Yes (Y)'	Amanda Hermosillo (b) (4)	23 Sep 2020 17:44:49

US3192486

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:12

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered '23 Sep 2020'	Amanda Hermosillo (b) (4)	23 Sep 2020 17:44:49

US3192486

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered '10:40'	Amanda Hermosillo (b) (4)	23 Sep 2020 17:44:49

US3192486

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:12

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User entered '23 Sep 2020 10:40'	System	23 Sep 2020 17:44:49

US3192486

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:12

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered '98.0' F	Amanda Hermosillo (b) (4)	23 Sep 2020 17:44:49

US3192486

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:12

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered 'Oral (Oral)'	Amanda Hermosillo (b) (4)	23 Sep 2020 17:44:49

US3192486
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:43:12
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered empty.	Amanda Hermosillo (b) (4)	23 Sep 2020 17:44:49

US3192486
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:43:12

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered '55'	Amanda Hermosillo (b) (4)	23 Sep 2020 17:44:49

US3192486
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:43:12
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User entered 'bpm'	System	23 Sep 2020 17:44:49

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered '12'	Amanda Hermosillo (b) (4)	23 Sep 2020 17:44:49

FDA-CBER-2022-1614-0415215

US3192486

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:12

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User entered 'breaths/min'	System	23 Sep 2020 17:44:49

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered '147'	Amanda Hermosillo (b) (4)	23 Sep 2020 17:44:49

FDA-CBER-2022-1614-0415217

US3192486

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:12

Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User entered 'mmHg'	System	23 Sep 2020 17:44:49

US3192486

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:12

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered '88'	Amanda Hermosillo (b) (4)	23 Sep 2020 17:44:49

FDA-CBER-2022-1614-0415219

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User entered 'mmHg'	System	23 Sep 2020 17:44:49

FDA-CBER-2022-1614-0415220

US3192486

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:43:12

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered 'Yes (Y)'	Tianna Young (b) (4) (b) (4)	23 Sep 2020 17:15:21

US3192486

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:43:12

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered '23 Sep 2020'	Tianna Young (b) (4) (b) (4)	23 Sep 2020 17:15:21

US3192486
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:43:12
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered 'Yes (Y)'	Tianna Young (b) (4) (b) (4)	23 Sep 2020 17:16:07

US3192486

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:43:12

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered empty.	Tianna Young (b) (4) (b) (4)	23 Sep 2020 17:16:07

US3192486

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:43:12

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)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered empty.	Tianna Young (b) (4) (b) (4)	23 Sep 2020 17:16:07

US3192486
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:43:12
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User entered 'MRNA-1273 OR PLACEBO'	System	23 Sep 2020 17:16:07

US3192486

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered '23 Sep 2020'	Tianna Young (b) (4) (b) (4)	23 Sep 2020 17:16:07

US3192486

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered '10:09'	Tianna Young (b) (4) (b) (4)	23 Sep 2020 17:16:07

Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User entered '23 Sep 2020 10:09'	System	23 Sep 2020 17:16:07

US3192486

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:43:12

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered 'Left Arm (LEFT ARM)'	Tianna Young (b) (4) (b) (4)	23 Sep 2020 17:16:07

US3192486

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:43:12

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User entered 'ONCE'	System	23 Sep 2020 17:16:07

US3192486

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:43:12

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User entered 'INTRAMUSCULAR'	System	23 Sep 2020 17:16:07

US3192486

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:43:12

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered 'Yes (Y)'	Tianna Young (b) (4) (b) (4)	23 Sep 2020 17:15:34

US3192486

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:43:12

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered '23 Sep 2020'	Tianna Young (b) (4) (b) (4)	23 Sep 2020 17:15:34

US3192486

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered '10:00'	Tianna Young (b) (4) (b) (4)	23 Sep 2020 17:15:34

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User entered '23 Sep 2020 10:00'	System	23 Sep 2020 17:15:34

FDA-CBER-2022-1614-0415236

Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab
Generated On: 09 Jun 2021 15:43:12

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered '23 Sep 2020'	Tianna Young (b) (4) (b) (4)	23 Sep 2020 17:15:47

US3192486

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:43:12

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Tianna Young (b) (4) (b) (4)	23 Sep 2020 17:15:47

US3192486

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:43:12

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered 'Yes (Y)'	Tianna Young (b) (4) (b) (4)	23 Sep 2020 17:15:47

US3192486

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered '10:05'	Tianna Young (b) (4) (b) (4)	23 Sep 2020 17:15:47

US3192486

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:43:12

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User entered '23 Sep 2020 10:05'	System	23 Sep 2020 17:15:47

US3192486

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:43:12

Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Tianna Young (b) (4) (b) (4)	23 Sep 2020 17:15:47

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered 'No (N)'	Tianna Young (b) (4) (b) (4)	23 Sep 2020 17:15:47

FDA-CBER-2022-1614-0415243

US3192486

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered empty.	Tianna Young (b) (4) (b) (4)	23 Sep 2020 17:15:47

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:43:12

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User entered empty.	System	23 Sep 2020 17:15:47

US3192486

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:43:12

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered 'Yes (Y)'	Tianna Young (b) (4) (b) (4)	23 Sep 2020 17:15:51

US3192486
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:43:12
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User entered '1'	System	23 Sep 2020 17:15:51

US3192486
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
Data entry locked.	System	23 Sep 2020 17:16:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Sep 2020 17:16:07

US3192486

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:43:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-23T10:33:06', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: 'b583e3d6-31e2-4d25-9ddd-f6f1f6111e13'	System	23 Sep 2020 17:33:58
User entered 'Yes (Y)'	System	23 Sep 2020 17:33:58

US3192486
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:43:12

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-23T10:33:32', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: 'b583e3d6-31e2-4d25-9ddd-f6f1f6111e13'	System	23 Sep 2020 17:33:58
User entered '98.0'	System	23 Sep 2020 17:33:58

US3192486

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-23T10:33:38', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: 'b583e3d6-31e2-4d25-9ddd-f6f1f6111e13'	System	23 Sep 2020 17:33:58
User entered 'Yes (Y)'	System	23 Sep 2020 17:33:58

US3192486
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:43:12
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).		01 Oct 2020 18:40:54
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'not related to the vaccine' (Site from System).	maggie Tono (b) (4) (b) (4)	26 Sep 2020 00:38:19
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	23 Sep 2020 17:33:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-23T10:33:47', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: 'b583e3d6-31e2-4d25-9ddd-f6f1f6111e13'	System	23 Sep 2020 17:33:58
User entered '1'	System	23 Sep 2020 17:33:58

US3192486

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:43:12

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-23T10:33:47', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: 'b583e3d6-31e2-4d25-9ddd-f6f1f6111e13'	System	23 Sep 2020 17:33:58
User entered '0'	System	23 Sep 2020 17:33:58

US3192486

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:43:12

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-23T10:33:54', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: 'b583e3d6-31e2-4d25-9ddd-f6f1f6111e13'	System	23 Sep 2020 17:33:58
User entered '23 Sep 2020 10:33'	System	23 Sep 2020 17:33:58

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
User entered '23 Sep 2020 10:29'	System	23 Sep 2020 17:16:07

US3192486

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:43:12

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
User entered '23 Sep 2020 12:59'	System	23 Sep 2020 17:16:07

US3192486
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
Data entry locked.	System	23 Sep 2020 17:16:07
User entered 'Day 1, after vaccination (at home)'	System	23 Sep 2020 17:16:07

US3192486
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:43:12
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-23T17:31:49', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '0d678afa-c75c-43a1-9366-d22e48a2de6e'	System	24 Sep 2020 00:32:15
User entered 'Yes (Y)'	System	24 Sep 2020 00:32:15

US3192486

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:43:12

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-23T17:31:58', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '0d678afa-c75c-43a1-9366-d22e48a2de6e'	System	24 Sep 2020 00:32:15
User entered '97.8'	System	24 Sep 2020 00:32:15

US3192486

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-23T17:32:04', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '0d678afa-c75c-43a1-9366-d22e48a2de6e'	System	24 Sep 2020 00:32:15
User entered 'No (N)'	System	24 Sep 2020 00:32:15

US3192486
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:43:12
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-23T17:32:12', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '0d678afa-c75c-43a1-9366-d22e48a2de6e'	System	24 Sep 2020 00:32:15
User entered '23 Sep 2020 17:32'	System	24 Sep 2020 00:32:15

US3192486

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:43:12

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
User entered '23 Sep 2020 13:54'	System	23 Sep 2020 17:16:07

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 17:16:07

FDA-CBER-2022-1614-0415263

US3192486
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
Data entry locked.	System	23 Sep 2020 17:16:07
User entered 'Day 2'	System	23 Sep 2020 17:16:07

US3192486

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:43:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-24T12:03:12', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: 'd62972c1-e6ca-46e4-b278-a4f5c3dd882e'	System	24 Sep 2020 19:03:45
User entered 'Yes (Y)'	System	24 Sep 2020 19:03:45

US3192486

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:43:12

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-24T12:03:20', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: 'd62972c1-e6ca-46e4-b278-a4f5c3dd882e'	System	24 Sep 2020 19:03:45
User entered '97.2'	System	24 Sep 2020 19:03:45

US3192486
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-24T12:03:26', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: 'd62972c1-e6ca-46e4-b278-a4f5c3dd882e'	System	24 Sep 2020 19:03:45
User entered 'No (N)'	System	24 Sep 2020 19:03:45

US3192486
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:43:12
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-24T12:03:31', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: 'd62972c1-e6ca-46e4-b278-a4f5c3dd882e'	System	24 Sep 2020 19:03:45
User entered '24 Sep 2020 12:03'	System	24 Sep 2020 19:03:45

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 17:16:07

US3192486

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:43:12

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 17:16:07

US3192486
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
Data entry locked.	System	23 Sep 2020 17:16:07
User entered 'Day 3'	System	23 Sep 2020 17:16:07

US3192486

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:43:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-25T12:00:32', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '2a3c42d2-c3d8-4691-95ff-8a9a4557f898'	System	25 Sep 2020 19:00:52
User entered 'Yes (Y)'	System	25 Sep 2020 19:00:52

US3192486
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:43:12

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-25T12:00:41', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '2a3c42d2-c3d8-4691-95ff-8a9a4557f898'	System	25 Sep 2020 19:00:52
User entered '97.5'	System	25 Sep 2020 19:00:52

US3192486

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-25T12:00:46', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '2a3c42d2-c3d8-4691-95ff-8a9a4557f898'	System	25 Sep 2020 19:00:52
User entered 'No (N)'	System	25 Sep 2020 19:00:52

US3192486
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:43:12
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-25T12:00:50', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '2a3c42d2-c3d8-4691-95ff-8a9a4557f898'	System	25 Sep 2020 19:00:52
User entered '25 Sep 2020 12:00'	System	25 Sep 2020 19:00:52

US3192486

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:43:12

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 17:16:07

US3192486
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:43:12
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 17:16:07

US3192486
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
Data entry locked.	System	23 Sep 2020 17:16:07
User entered 'Day 4'	System	23 Sep 2020 17:16:07

US3192486

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:43:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-26T13:17:46', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '553c167a-b78f-488e-80f8-ca9147e49880'	System	26 Sep 2020 20:18:06
User entered 'Yes (Y)'	System	26 Sep 2020 20:18:06

US3192486

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:43:12

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-26T13:17:54', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '553c167a-b78f-488e-80f8-ca9147e49880'	System	26 Sep 2020 20:18:06
User entered '97.6'	System	26 Sep 2020 20:18:06

US3192486

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-26T13:17:59', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '553c167a-b78f-488e-80f8-ca9147e49880'	System	26 Sep 2020 20:18:06
User entered 'No (N)'	System	26 Sep 2020 20:18:06

FDA-CBER-2022-1614-0415281

US3192486
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:43:12
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-26T13:18:03', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '553c167a-b78f-488e-80f8-ca9147e49880'	System	26 Sep 2020 20:18:06
User entered '26 Sep 2020 13:18'	System	26 Sep 2020 20:18:06

US3192486

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:43:12

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
User entered '26 Sep 2020 12:00'	System	23 Sep 2020 17:16:07

US3192486

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:43:12

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
User entered '27 Sep 2020 11:59'	System	23 Sep 2020 17:16:07

US3192486
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
Data entry locked.	System	23 Sep 2020 17:16:07
User entered 'Day 5'	System	23 Sep 2020 17:16:07

US3192486

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:43:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-27T12:00:37', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '5d6bf8bb-4db9-4226-a780-6e9701642592'	System	27 Sep 2020 19:01:08
User entered 'Yes (Y)'	System	27 Sep 2020 19:01:08

US3192486

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:43:12

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-27T12:00:54', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '5d6bf8bb-4db9-4226-a780-6e9701642592'	System	27 Sep 2020 19:01:08
User entered '96.8'	System	27 Sep 2020 19:01:08

US3192486

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-27T12:00:59', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '5d6bf8bb-4db9-4226-a780-6e9701642592'	System	27 Sep 2020 19:01:08
User entered 'No (N)'	System	27 Sep 2020 19:01:08

US3192486

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:43:12

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-27T12:01:02', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '5d6bf8bb-4db9-4226-a780-6e9701642592'	System	27 Sep 2020 19:01:08
User entered '27 Sep 2020 12:01'	System	27 Sep 2020 19:01:08

US3192486
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:43:12

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
User entered '27 Sep 2020 12:00'	System	23 Sep 2020 17:16:07

US3192486

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:43:12

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
User entered '28 Sep 2020 11:59'	System	23 Sep 2020 17:16:07

US3192486
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
Data entry locked.	System	23 Sep 2020 17:16:07
User entered 'Day 6'	System	23 Sep 2020 17:16:07

US3192486

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:43:12

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-28T12:30:59', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '3f46941f-d65c-4551-9737-73bc7eda30cf'	System	28 Sep 2020 19:31:17
User entered 'Yes (Y)'	System	28 Sep 2020 19:31:17

US3192486
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:43:12

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-28T12:31:06', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '3f46941f-d65c-4551-9737-73bc7eda30cf'	System	28 Sep 2020 19:31:17
User entered '98.0'	System	28 Sep 2020 19:31:17

US3192486

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-28T12:31:11', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '3f46941f-d65c-4551-9737-73bc7eda30cf'	System	28 Sep 2020 19:31:17
User entered 'No (N)'	System	28 Sep 2020 19:31:17

US3192486
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:43:12
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-28T12:31:14', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '3f46941f-d65c-4551-9737-73bc7eda30cf'	System	28 Sep 2020 19:31:17
User entered '28 Sep 2020 12:31'	System	28 Sep 2020 19:31:17

US3192486

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:43:12

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
User entered '28 Sep 2020 12:00'	System	23 Sep 2020 17:16:07

US3192486

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:43:12

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
User entered '29 Sep 2020 11:59'	System	23 Sep 2020 17:16:07

US3192486
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
Data entry locked.	System	23 Sep 2020 17:16:07
User entered 'Day 7'	System	23 Sep 2020 17:16:07

Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:43:12
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30

US3192486
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:43:12
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30

US3192486

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30

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US3192486
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:43:12

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30

US3192486
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:43:12
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30

US3192486
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:43:12
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30

US3192486

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:43:12

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
User entered '29 Sep 2020 12:00'	System	23 Sep 2020 17:16:07

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
User entered '30 Sep 2020 11:59'	System	23 Sep 2020 17:16:07

FDA-CBER-2022-1614-0415307

US3192486
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
Data entry locked.	System	23 Sep 2020 17:16:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Sep 2020 17:16:07

US3192486

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:43:12

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-23T10:34:05', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: 'ff1ca374-d31c-4e0f-b0fa-5501451d257e'	System	23 Sep 2020 17:34:24
User entered 'None (1)'	System	23 Sep 2020 17:34:24

US3192486
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:43:12

Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-23T10:34:11', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: 'ff1ca374-d31c-4e0f-b0fa-5501451d257e'	System	23 Sep 2020 17:34:24
User entered 'No (N)'	System	23 Sep 2020 17:34:24

US3192486

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:43:12

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-23T10:34:14', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: 'ff1ca374-d31c-4e0f-b0fa-5501451d257e'	System	23 Sep 2020 17:34:24
User entered 'No (N)'	System	23 Sep 2020 17:34:24

US3192486

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:43:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-23T10:34:19', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: 'ff1ca374-d31c-4e0f-b0fa-5501451d257e'	System	23 Sep 2020 17:34:24
User entered 'None (1)'	System	23 Sep 2020 17:34:24

US3192486
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:43:12
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-23T10:34:22', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: 'ff1ca374-d31c-4e0f-b0fa-5501451d257e'	System	23 Sep 2020 17:34:24
User entered '23 Sep 2020 10:34'	System	23 Sep 2020 17:34:24

US3192486

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:43:12

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
User entered '23 Sep 2020 10:29'	System	23 Sep 2020 17:16:07

US3192486

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:43:12

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
User entered '23 Sep 2020 12:59'	System	23 Sep 2020 17:16:07

US3192486
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
Data entry locked.	System	23 Sep 2020 17:16:07
User entered 'Day 1, after vaccination (at home)'	System	23 Sep 2020 17:16:07

US3192486

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:43:12

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-23T17:32:19', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '08de5117-8527-404c-820e-2d893fbc0830'	System	24 Sep 2020 00:32:36
User entered 'None (1)'	System	24 Sep 2020 00:32:36

US3192486
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:43:12
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-23T17:32:23', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '08de5117-8527-404c-820e-2d893fbc0830'	System	24 Sep 2020 00:32:36
User entered 'No (N)'	System	24 Sep 2020 00:32:36

US3192486

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:43:12

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-23T17:32:26', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '08de5117-8527-404c-820e-2d893fbc0830'	System	24 Sep 2020 00:32:36
User entered 'No (N)'	System	24 Sep 2020 00:32:36

US3192486

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:43:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-23T17:32:31', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '08de5117-8527-404c-820e-2d893fbc0830'	System	24 Sep 2020 00:32:36
User entered 'None (1)'	System	24 Sep 2020 00:32:36

US3192486
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:43:12
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-23T17:32:34', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '08de5117-8527-404c-820e-2d893fbc0830'	System	24 Sep 2020 00:32:36
User entered '23 Sep 2020 17:32'	System	24 Sep 2020 00:32:36

Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:43:12

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
User entered '23 Sep 2020 13:54'	System	23 Sep 2020 17:16:07

US3192486

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:43:12

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 17:16:07

US3192486
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
Data entry locked.	System	23 Sep 2020 17:16:07
User entered 'Day 2'	System	23 Sep 2020 17:16:07

US3192486

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:43:12

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-24T12:03:41', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '5fbcaa49-ba3d-4c0e-a862-3bcbb5481b2c'	System	24 Sep 2020 19:04:04
User entered 'None (1)'	System	24 Sep 2020 19:04:04

US3192486

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:43:12

Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-24T12:03:45', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '5fbcaa49-ba3d-4c0e-a862-3bcbb5481b2c'	System	24 Sep 2020 19:04:04
User entered 'No (N)'	System	24 Sep 2020 19:04:04

US3192486
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:43:12
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-24T12:03:50', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '5fbcaa49-ba3d-4c0e-a862-3bcbb5481b2c'	System	24 Sep 2020 19:04:04
User entered 'No (N)'	System	24 Sep 2020 19:04:04

US3192486

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:43:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-24T12:03:57', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '5fbcaa49-ba3d-4c0e-a862-3bcbb5481b2c'	System	24 Sep 2020 19:04:04
User entered 'None (1)'	System	24 Sep 2020 19:04:04

US3192486
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:43:12
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-24T12:04:00', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '5fbcaa49-ba3d-4c0e-a862-3bcbb5481b2c'	System	24 Sep 2020 19:04:04
User entered '24 Sep 2020 12:04'	System	24 Sep 2020 19:04:04

US3192486
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:43:12
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 17:16:07

US3192486
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:43:12
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 17:16:07

US3192486
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
Data entry locked.	System	23 Sep 2020 17:16:07
User entered 'Day 3'	System	23 Sep 2020 17:16:07

US3192486

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:43:12

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-25T12:00:55', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '873f354c-55ed-4e5e-b2c2-b92434638145'	System	25 Sep 2020 19:01:18
User entered 'None (1)'	System	25 Sep 2020 19:01:18

US3192486
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:43:12

Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-25T12:00:59', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '873f354c-55ed-4e5e-b2c2-b92434638145'	System	25 Sep 2020 19:01:18
User entered 'No (N)'	System	25 Sep 2020 19:01:18

US3192486

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:43:12

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-25T12:01:02', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '873f354c-55ed-4e5e-b2c2-b92434638145'	System	25 Sep 2020 19:01:18
User entered 'No (N)'	System	25 Sep 2020 19:01:18

US3192486

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:43:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-25T12:01:06', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '873f354c-55ed-4e5e-b2c2-b92434638145'	System	25 Sep 2020 19:01:18
User entered 'None (1)'	System	25 Sep 2020 19:01:18

US3192486

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:43:12

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-25T12:01:11', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '873f354c-55ed-4e5e-b2c2-b92434638145'	System	25 Sep 2020 19:01:18
User entered '25 Sep 2020 12:01'	System	25 Sep 2020 19:01:18

US3192486
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:43:12
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 17:16:07

US3192486

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:43:12

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 17:16:07

US3192486
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
Data entry locked.	System	23 Sep 2020 17:16:07
User entered 'Day 4'	System	23 Sep 2020 17:16:07

US3192486

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:43:12

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-26T13:18:08', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '7f1eb2b5-8722-42b7-92f8-000a72cf7c4a'	System	26 Sep 2020 20:18:35
User entered 'None (1)'	System	26 Sep 2020 20:18:35

US3192486
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:43:12
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-26T13:18:12', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '7f1eb2b5-8722-42b7-92f8-000a72cf7c4a'	System	26 Sep 2020 20:18:35
User entered 'No (N)'	System	26 Sep 2020 20:18:35

US3192486
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:43:12
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-26T13:18:16', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '7f1eb2b5-8722-42b7-92f8-000a72cf7c4a'	System	26 Sep 2020 20:18:35
User entered 'No (N)'	System	26 Sep 2020 20:18:35

US3192486
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:43:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-26T13:18:24', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '7f1eb2b5-8722-42b7-92f8-000a72cf7c4a'	System	26 Sep 2020 20:18:35
User entered 'None (1)'	System	26 Sep 2020 20:18:35

US3192486

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:43:12

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-26T13:18:28', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '7f1eb2b5-8722-42b7-92f8-000a72cf7c4a'	System	26 Sep 2020 20:18:35
User entered '26 Sep 2020 13:18'	System	26 Sep 2020 20:18:35

Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:43:12
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
User entered '26 Sep 2020 12:00'	System	23 Sep 2020 17:16:07

US3192486
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:43:12
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
User entered '27 Sep 2020 11:59'	System	23 Sep 2020 17:16:07

US3192486
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
Data entry locked.	System	23 Sep 2020 17:16:07
User entered 'Day 5'	System	23 Sep 2020 17:16:07

US3192486

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:43:12

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-27T12:01:07', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '71fdf715-d5c3-4d06-8a23-f7e2377dc958'	System	27 Sep 2020 19:01:26
User entered 'None (1)'	System	27 Sep 2020 19:01:26

US3192486

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:43:12

Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-27T12:01:12', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '71fdf715-d5c3-4d06-8a23-f7e2377dc958'	System	27 Sep 2020 19:01:26
User entered 'No (N)'	System	27 Sep 2020 19:01:26

US3192486

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:43:12

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-27T12:01:15', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '71fdf715-d5c3-4d06-8a23-f7e2377dc958'	System	27 Sep 2020 19:01:26
User entered 'No (N)'	System	27 Sep 2020 19:01:26

US3192486

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:43:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-27T12:01:18', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '71fdf715-d5c3-4d06-8a23-f7e2377dc958'	System	27 Sep 2020 19:01:26
User entered 'None (1)'	System	27 Sep 2020 19:01:26

US3192486
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:43:12
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-27T12:01:23', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '71fdf715-d5c3-4d06-8a23-f7e2377dc958'	System	27 Sep 2020 19:01:26
User entered '27 Sep 2020 12:01'	System	27 Sep 2020 19:01:26

US3192486
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:43:12
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
User entered '27 Sep 2020 12:00'	System	23 Sep 2020 17:16:07

US3192486
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:43:12
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
User entered '28 Sep 2020 11:59'	System	23 Sep 2020 17:16:07

US3192486
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
Data entry locked.	System	23 Sep 2020 17:16:07
User entered 'Day 6'	System	23 Sep 2020 17:16:07

US3192486

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:43:12

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-28T12:31:19', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '405d069a-7a3e-4907-9a0c-e325df839ca7'	System	28 Sep 2020 19:31:37
User entered 'None (1)'	System	28 Sep 2020 19:31:37

US3192486

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:43:12

Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-28T12:31:23', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '405d069a-7a3e-4907-9a0c-e325df839ca7'	System	28 Sep 2020 19:31:37
User entered 'No (N)'	System	28 Sep 2020 19:31:37

US3192486
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:43:12

Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-28T12:31:26', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '405d069a-7a3e-4907-9a0c-e325df839ca7'	System	28 Sep 2020 19:31:37
User entered 'No (N)'	System	28 Sep 2020 19:31:37

US3192486

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:43:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-28T12:31:31', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '405d069a-7a3e-4907-9a0c-e325df839ca7'	System	28 Sep 2020 19:31:37
User entered 'None (1)'	System	28 Sep 2020 19:31:37

US3192486

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:43:12

PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-28T12:31:34', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '405d069a-7a3e-4907-9a0c-e325df839ca7'	System	28 Sep 2020 19:31:37
User entered '28 Sep 2020 12:31'	System	28 Sep 2020 19:31:37

US3192486

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:43:12

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
User entered '28 Sep 2020 12:00'	System	23 Sep 2020 17:16:07

US3192486

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:43:12

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
User entered '29 Sep 2020 11:59'	System	23 Sep 2020 17:16:07

US3192486
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
Data entry locked.	System	23 Sep 2020 17:16:07
User entered 'Day 7'	System	23 Sep 2020 17:16:07

US3192486

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:43:12

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30

US3192486
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:43:12

Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30

US3192486

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:43:12

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30

Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:43:12
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30

US3192486

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:43:12

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)	25 Feb 2021 18:58:30

US3192486

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:43:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30

US3192486
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:43:12
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30

US3192486
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:43:12
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
User entered '29 Sep 2020 12:00'	System	23 Sep 2020 17:16:07

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
User entered '30 Sep 2020 11:59'	System	23 Sep 2020 17:16:07

US3192486
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
Data entry locked.	System	23 Sep 2020 17:16:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Sep 2020 17:16:07

US3192486
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:43:12
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-23T10:34:27', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: 'ba1d2c03-9c6c-455c-b057-3867b1f4c2b0'	System	23 Sep 2020 17:34:56
User entered 'None (0)'	System	23 Sep 2020 17:34:56

US3192486
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:43:12
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-23T10:34:31', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: 'ba1d2c03-9c6c-455c-b057-3867b1f4c2b0'	System	23 Sep 2020 17:34:56
User entered 'None (0)'	System	23 Sep 2020 17:34:56

US3192486
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:43:12
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-23T10:34:34', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: 'ba1d2c03-9c6c-455c-b057-3867b1f4c2b0'	System	23 Sep 2020 17:34:56
User entered 'None (0)'	System	23 Sep 2020 17:34:56

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US3192486
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:43:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-23T10:34:38', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: 'ba1d2c03-9c6c-455c-b057-3867b1f4c2b0'	System	23 Sep 2020 17:34:56
User entered 'None (0)'	System	23 Sep 2020 17:34:56

US3192486
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:43:12
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-23T10:34:41', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: 'ba1d2c03-9c6c-455c-b057-3867b1f4c2b0'	System	23 Sep 2020 17:34:56
User entered 'None (0)'	System	23 Sep 2020 17:34:56

US3192486
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:43:12
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-23T10:34:43', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: 'ba1d2c03-9c6c-455c-b057-3867b1f4c2b0'	System	23 Sep 2020 17:34:56
User entered 'None (0)'	System	23 Sep 2020 17:34:56

US3192486

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:43:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-23T10:34:49', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: 'ba1d2c03-9c6c-455c-b057-3867b1f4c2b0'	System	23 Sep 2020 17:34:56
User entered 'No (N)'	System	23 Sep 2020 17:34:56

US3192486

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:43:12

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-23T10:34:52', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: 'ba1d2c03-9c6c-455c-b057-3867b1f4c2b0'	System	23 Sep 2020 17:34:56
User entered '23 Sep 2020 10:34'	System	23 Sep 2020 17:34:56

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
User entered '23 Sep 2020 10:29'	System	23 Sep 2020 17:16:07

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Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:43:12
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
User entered '23 Sep 2020 12:59'	System	23 Sep 2020 17:16:07

US3192486
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
Data entry locked.	System	23 Sep 2020 17:16:07
User entered 'Day 1, after vaccination (at home)'	System	23 Sep 2020 17:16:07

US3192486
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:43:12
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-23T17:32:39', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: 'db41d76e-2969-4fa3-b693-73d42881450d'	System	24 Sep 2020 00:33:00
User entered 'None (0)'	System	24 Sep 2020 00:33:00

US3192486
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:43:12
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-23T17:32:42', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: 'db41d76e-2969-4fa3-b693-73d42881450d'	System	24 Sep 2020 00:33:00
User entered 'None (0)'	System	24 Sep 2020 00:33:00

US3192486
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:43:12
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-23T17:32:45', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: 'db41d76e-2969-4fa3-b693-73d42881450d'	System	24 Sep 2020 00:33:00
User entered 'None (0)'	System	24 Sep 2020 00:33:00

US3192486

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:43:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-23T17:32:48', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: 'db41d76e-2969-4fa3-b693-73d42881450d'	System	24 Sep 2020 00:33:00
User entered 'None (0)'	System	24 Sep 2020 00:33:00

US3192486
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:43:12
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-23T17:32:50', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: 'db41d76e-2969-4fa3-b693-73d42881450d'	System	24 Sep 2020 00:33:00
User entered 'None (0)'	System	24 Sep 2020 00:33:00

US3192486

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:43:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-23T17:32:52', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: 'db41d76e-2969-4fa3-b693-73d42881450d'	System	24 Sep 2020 00:33:00
User entered 'None (0)'	System	24 Sep 2020 00:33:00

US3192486

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:43:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-23T17:32:56', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: 'db41d76e-2969-4fa3-b693-73d42881450d'	System	24 Sep 2020 00:33:00
User entered 'No (N)'	System	24 Sep 2020 00:33:00

US3192486

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:43:12

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-23T17:32:58', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: 'db41d76e-2969-4fa3-b693-73d42881450d'	System	24 Sep 2020 00:33:00
User entered '23 Sep 2020 17:32'	System	24 Sep 2020 00:33:00

US3192486

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:43:12

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
User entered '23 Sep 2020 13:54'	System	23 Sep 2020 17:16:07

US3192486
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:43:12
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 17:16:07

US3192486
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
Data entry locked.	System	23 Sep 2020 17:16:07
User entered 'Day 2'	System	23 Sep 2020 17:16:07

US3192486
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:43:12
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-24T12:04:06', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '5adba159-102a-4c03-bcc9-fe41db07e246'	System	24 Sep 2020 19:04:45
User entered 'None (0)'	System	24 Sep 2020 19:04:45

US3192486
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:43:12
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-24T12:04:09', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '5adba159-102a-4c03-bcc9-fe41db07e246'	System	24 Sep 2020 19:04:45
User entered 'None (0)'	System	24 Sep 2020 19:04:45

US3192486

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:43:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-24T12:04:16', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '5adba159-102a-4c03-bcc9-fe41db07e246'	System	24 Sep 2020 19:04:45
User entered 'None (0)'	System	24 Sep 2020 19:04:45

US3192486

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:43:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-24T12:04:21', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '5adba159-102a-4c03-bcc9-fe41db07e246'	System	24 Sep 2020 19:04:45
User entered 'None (0)'	System	24 Sep 2020 19:04:45

US3192486
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:43:12
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-24T12:04:25', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '5adba159-102a-4c03-bcc9-fe41db07e246'	System	24 Sep 2020 19:04:45
User entered 'None (0)'	System	24 Sep 2020 19:04:45

US3192486

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:43:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-24T12:04:31', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '5adba159-102a-4c03-bcc9-fe41db07e246'	System	24 Sep 2020 19:04:45
User entered 'None (0)'	System	24 Sep 2020 19:04:45

US3192486

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:43:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-24T12:04:40', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '5adba159-102a-4c03-bcc9-fe41db07e246'	System	24 Sep 2020 19:04:45
User entered 'No (N)'	System	24 Sep 2020 19:04:45

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US3192486

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:43:12

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-24T12:04:42', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '5adba159-102a-4c03-bcc9-fe41db07e246'	System	24 Sep 2020 19:04:45
User entered '24 Sep 2020 12:04'	System	24 Sep 2020 19:04:45

US3192486

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:43:12

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 17:16:07

US3192486

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:43:12

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 17:16:07

US3192486
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
Data entry locked.	System	23 Sep 2020 17:16:07
User entered 'Day 3'	System	23 Sep 2020 17:16:07

US3192486
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:43:12
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-25T12:01:16', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '0721ee1f-097f-41e0-bb57-3a5b337a5e7a'	System	25 Sep 2020 19:01:44
User entered 'None (0)'	System	25 Sep 2020 19:01:44

US3192486

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:43:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-25T12:01:19', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '0721ee1f-097f-41e0-bb57-3a5b337a5e7a'	System	25 Sep 2020 19:01:44
User entered 'None (0)'	System	25 Sep 2020 19:01:44

US3192486
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:43:12
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-25T12:01:23', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '0721ee1f-097f-41e0-bb57-3a5b337a5e7a'	System	25 Sep 2020 19:01:44
User entered 'None (0)'	System	25 Sep 2020 19:01:44

US3192486

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:43:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-25T12:01:27', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '0721ee1f-097f-41e0-bb57-3a5b337a5e7a'	System	25 Sep 2020 19:01:44
User entered 'None (0)'	System	25 Sep 2020 19:01:44

US3192486
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:43:12
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-25T12:01:31', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '0721ee1f-097f-41e0-bb57-3a5b337a5e7a'	System	25 Sep 2020 19:01:44
User entered 'None (0)'	System	25 Sep 2020 19:01:44

US3192486
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:43:12
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-25T12:01:34', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '0721ee1f-097f-41e0-bb57-3a5b337a5e7a'	System	25 Sep 2020 19:01:44
User entered 'None (0)'	System	25 Sep 2020 19:01:44

US3192486

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:43:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-25T12:01:39', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '0721ee1f-097f-41e0-bb57-3a5b337a5e7a'	System	25 Sep 2020 19:01:44
User entered 'No (N)'	System	25 Sep 2020 19:01:44

US3192486

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:43:12

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-25T12:01:42', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '0721ee1f-097f-41e0-bb57-3a5b337a5e7a'	System	25 Sep 2020 19:01:44
User entered '25 Sep 2020 12:01'	System	25 Sep 2020 19:01:44

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 17:16:07

US3192486

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:43:12

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 17:16:07

US3192486
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
Data entry locked.	System	23 Sep 2020 17:16:07
User entered 'Day 4'	System	23 Sep 2020 17:16:07

US3192486
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:43:12
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-26T13:18:33', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '4ee9ed00-b6a5-4e86-b432-e8668ffaea37'	System	26 Sep 2020 20:18:58
User entered 'None (0)'	System	26 Sep 2020 20:18:58

US3192486

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:43:12

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-26T13:18:36', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '4ee9ed00-b6a5-4e86-b432-e8668ffaea37'	System	26 Sep 2020 20:18:58
User entered 'None (0)'	System	26 Sep 2020 20:18:58

US3192486
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:43:12
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-26T13:18:39', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '4ee9ed00-b6a5-4e86-b432-e8668ffaea37'	System	26 Sep 2020 20:18:58
User entered 'None (0)'	System	26 Sep 2020 20:18:58

US3192486
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:43:12
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-26T13:18:43', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '4ee9ed00-b6a5-4e86-b432-e8668ffaea37'	System	26 Sep 2020 20:18:58
User entered 'None (0)'	System	26 Sep 2020 20:18:58

US3192486
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:43:12
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-26T13:18:47', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '4ee9ed00-b6a5-4e86-b432-e8668ffaea37'	System	26 Sep 2020 20:18:58
User entered 'None (0)'	System	26 Sep 2020 20:18:58

US3192486
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:43:12
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-26T13:18:50', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '4ee9ed00-b6a5-4e86-b432-e8668ffaea37'	System	26 Sep 2020 20:18:58
User entered 'None (0)'	System	26 Sep 2020 20:18:58

US3192486
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:43:12
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-26T13:18:53', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '4ee9ed00-b6a5-4e86-b432-e8668ffaea37'	System	26 Sep 2020 20:18:58
User entered 'No (N)'	System	26 Sep 2020 20:18:58

US3192486

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:43:12

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-26T13:18:56', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '4ee9ed00-b6a5-4e86-b432-e8668ffaea37'	System	26 Sep 2020 20:18:58
User entered '26 Sep 2020 13:18'	System	26 Sep 2020 20:18:58

US3192486

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:43:12

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
User entered '26 Sep 2020 12:00'	System	23 Sep 2020 17:16:07

US3192486

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:43:12

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
User entered '27 Sep 2020 11:59'	System	23 Sep 2020 17:16:07

US3192486
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
Data entry locked.	System	23 Sep 2020 17:16:07
User entered 'Day 5'	System	23 Sep 2020 17:16:07

US3192486
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:43:12
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-27T12:01:28', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: 'fa20ab0a-ce9d-4b33-a745-1368543209a6'	System	27 Sep 2020 19:01:55
User entered 'None (0)'	System	27 Sep 2020 19:01:55

US3192486
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:43:12
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-27T12:01:30', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: 'fa20ab0a-ce9d-4b33-a745-1368543209a6'	System	27 Sep 2020 19:01:55
User entered 'None (0)'	System	27 Sep 2020 19:01:55

US3192486
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:43:12
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-27T12:01:33', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: 'fa20ab0a-ce9d-4b33-a745-1368543209a6'	System	27 Sep 2020 19:01:55
User entered 'None (0)'	System	27 Sep 2020 19:01:55

US3192486

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:43:12

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-27T12:01:36', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: 'fa20ab0a-ce9d-4b33-a745-1368543209a6'	System	27 Sep 2020 19:01:55
User entered 'None (0)'	System	27 Sep 2020 19:01:55

US3192486

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:43:12

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-27T12:01:41', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: 'fa20ab0a-ce9d-4b33-a745-1368543209a6'	System	27 Sep 2020 19:01:55
User entered 'None (0)'	System	27 Sep 2020 19:01:55

US3192486
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:43:12
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-27T12:01:44', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: 'fa20ab0a-ce9d-4b33-a745-1368543209a6'	System	27 Sep 2020 19:01:55
User entered 'None (0)'	System	27 Sep 2020 19:01:55

US3192486

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:43:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-27T12:01:49', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: 'fa20ab0a-ce9d-4b33-a745-1368543209a6'	System	27 Sep 2020 19:01:55
User entered 'No (N)'	System	27 Sep 2020 19:01:55

US3192486

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:43:12

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-27T12:01:52', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: 'fa20ab0a-ce9d-4b33-a745-1368543209a6'	System	27 Sep 2020 19:01:55
User entered '27 Sep 2020 12:01'	System	27 Sep 2020 19:01:55

US3192486

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:43:12

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
User entered '27 Sep 2020 12:00'	System	23 Sep 2020 17:16:07

US3192486

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:43:12

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
User entered '28 Sep 2020 11:59'	System	23 Sep 2020 17:16:07

US3192486
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
Data entry locked.	System	23 Sep 2020 17:16:07
User entered 'Day 6'	System	23 Sep 2020 17:16:07

US3192486
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:43:12
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-28T12:31:39', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '30eef118-2158-4abf-a762-864117bac671'	System	28 Sep 2020 19:32:00
User entered 'None (0)'	System	28 Sep 2020 19:32:00

US3192486
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:43:12
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-28T12:31:42', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '30eef118-2158-4abf-a762-864117bac671'	System	28 Sep 2020 19:32:00
User entered 'None (0)'	System	28 Sep 2020 19:32:00

US3192486

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:43:12

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-28T12:31:44', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '30eef118-2158-4abf-a762-864117bac671'	System	28 Sep 2020 19:32:00
User entered 'None (0)'	System	28 Sep 2020 19:32:00

US3192486
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:43:12
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-28T12:31:46', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '30eef118-2158-4abf-a762-864117bac671'	System	28 Sep 2020 19:32:00
User entered 'None (0)'	System	28 Sep 2020 19:32:00

FDA-CBER-2022-1614-0415444

US3192486
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:43:12
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-28T12:31:48', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '30eef118-2158-4abf-a762-864117bac671'	System	28 Sep 2020 19:32:00
User entered 'None (0)'	System	28 Sep 2020 19:32:00

US3192486

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:43:12

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-28T12:31:51', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '30eef118-2158-4abf-a762-864117bac671'	System	28 Sep 2020 19:32:00
User entered 'None (0)'	System	28 Sep 2020 19:32:00

US3192486

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:43:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-28T12:31:56', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '30eef118-2158-4abf-a762-864117bac671'	System	28 Sep 2020 19:32:00
User entered 'No (N)'	System	28 Sep 2020 19:32:00

US3192486

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:43:12

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-09-28T12:31:58', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '30eef118-2158-4abf-a762-864117bac671'	System	28 Sep 2020 19:32:00
User entered '28 Sep 2020 12:31'	System	28 Sep 2020 19:32:00

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
User entered '28 Sep 2020 12:00'	System	23 Sep 2020 17:16:07

US3192486

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:43:12

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
User entered '29 Sep 2020 11:59'	System	23 Sep 2020 17:16:07

US3192486
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
Data entry locked.	System	23 Sep 2020 17:16:07
User entered 'Day 7'	System	23 Sep 2020 17:16:07

US3192486
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:43:12
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30

US3192486
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:43:12
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30

US3192486
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:43:12
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30

US3192486
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:43:12
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30

US3192486
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:43:12
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30

US3192486

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:43:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30

US3192486

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:43:12

PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30

US3192486

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:43:12

PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
User entered '29 Sep 2020 12:00'	System	23 Sep 2020 17:16:07

PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
User entered '30 Sep 2020 11:59'	System	23 Sep 2020 17:16:07

US3192486

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:12

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered 'Yes (Y)'	Zoe Sesma (b) (4) (b) (4)	30 Sep 2020 21:30:26

US3192486

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:12

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered '30 Sep 2020'	Zoe Sesma (b) (4) (b) (4)	30 Sep 2020 21:30:26

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered 'Contact Made (CONTACT MADE)'	Zoe Sesma (b) (4) (b) (4)	30 Sep 2020 21:30:26

US3192486

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:12

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered empty.	Zoe Sesma (b) (4) (b) (4)	30 Sep 2020 21:30:26

US3192486
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:43:12

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered 'Yes (Y)'	Zoe Sesma (b) (4) (b) (4)	30 Sep 2020 21:30:29

US3192486

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:43:12

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User entered '1'	System	30 Sep 2020 21:30:29

US3192486

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:12

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:59:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Oct 2020 22:56:26

US3192486

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:12

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:59:55
User entered '10 Oct 2020'	(b) (4) (b) (4), (b) (6)	10 Oct 2020 22:56:26

US3192486

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:12

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:59:55
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	10 Oct 2020 22:56:26

FDA-CBER-2022-1614-0415470

US3192486

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:12

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered empty.	(b) (4), (b) (6)	10 Oct 2020 22:56:26

US3192486

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:43:12

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Oct 2020 22:56:31

US3192486
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:43:12
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User entered '1'	System	10 Oct 2020 22:56:31

US3192486
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:43:12

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Oct 2020 19:17:38

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:59:55
User entered '14 Oct 2020'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 19:17:38

US3192486

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:12

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:59:55
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 19:17:38

US3192486

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:12

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 02:59:55
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 19:17:38

US3192486

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:43:12

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 02:59:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Oct 2020 19:17:43

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User entered '1'	System	21 Oct 2020 19:17:43

US3192486
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:43:12
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered 'Yes (Y)'	Crystal Mata (b) (4) (b) (4)	11 Nov 2020 01:43:33

US3192486

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:43:12

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered '18 Oct 2020'	Crystal Mata (b) (4) (b) (4)	11 Nov 2020 01:43:33

US3192486

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered 'Clinic (Clinic)'	Crystal Mata (b) (4) (b) (4)	11 Nov 2020 01:43:33

FDA-CBER-2022-1614-0415482

US3192486
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:43:12
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User entered 'VISIT3'	System	11 Nov 2020 01:43:33

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered 'Yes (Y)'	Crystal Mata (b) (4) (b) (4)	11 Nov 2020 01:44:29

FDA-CBER-2022-1614-0415484

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered '18 Oct 2020'	Crystal Mata (b) (4) (b) (4)	11 Nov 2020 01:44:29

US3192486
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered '08:28'	Crystal Mata (b) (4) (b) (4)	11 Nov 2020 01:44:29

US3192486
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:43:12
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User entered '18 Oct 2020 08:28'	System	11 Nov 2020 01:44:29

US3192486
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:43:12

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered '97.2' F	Crystal Mata (b) (4) (b) (4)	11 Nov 2020 01:44:29

US3192486

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:12

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered 'Oral (Oral)'	Crystal Mata (b) (4) (b) (4)	11 Nov 2020 01:44:29

US3192486
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:43:12
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered empty.	Crystal Mata (b) (4) (b) (4)	11 Nov 2020 01:44:29

US3192486
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:43:12

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered '76'	Crystal Mata (b) (4) (b) (4)	11 Nov 2020 01:44:29

US3192486
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:43:12
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User entered 'bpm'	System	11 Nov 2020 01:44:29

US3192486
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:43:12

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered '14'	Crystal Mata (b) (4) (b) (4)	11 Nov 2020 01:44:29

US3192486
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:43:12
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User entered 'breaths/min'	System	11 Nov 2020 01:44:29

US3192486
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:43:12

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered '150'	Crystal Mata (b) (4) (b) (4)	11 Nov 2020 01:44:29

US3192486
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:43:12
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User entered 'mmHg'	System	11 Nov 2020 01:44:29

US3192486
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:43:12

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered '86'	Crystal Mata (b) (4) (b) (4)	11 Nov 2020 01:44:29

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User entered 'mmHg'	System	11 Nov 2020 01:44:29

FDA-CBER-2022-1614-0415498

US3192486
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:43:12
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07

US3192486
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:43:12

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07

US3192486

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:43:12

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered 'Yes (Y)'	Crystal Mata (b) (4) (b) (4)	11 Nov 2020 01:45:05

US3192486

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:43:12

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered '18 Oct 2020'	Crystal Mata (b) (4) (b) (4)	11 Nov 2020 01:45:05

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered 'Yes (Y)'	Crystal Mata (b) (4) (b) (4)	11 Nov 2020 01:45:28

FDA-CBER-2022-1614-0415503

US3192486

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:43:12

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered '18 Oct 2020'	Crystal Mata (b) (4) (b) (4)	11 Nov 2020 01:45:28

US3192486

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered '08:37'	Crystal Mata (b) (4) (b) (4)	11 Nov 2020 01:45:28

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User entered '18 Oct 2020 08:37'	System	11 Nov 2020 01:45:28

US3192486

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:43:12

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	14 Feb 2021 03:00:06
User entered 'Yes (Y)'	Crystal Mata (b) (4) (b) (4)	11 Nov 2020 01:45:35

US3192486

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:43:12

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User entered '1'	System	11 Nov 2020 01:45:35

US3192486
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:09:30
Data entry locked.	System	26 Aug 2020 16:08:28
User entered 'Day 64'	System	26 Aug 2020 16:08:28

US3192486

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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)	24 Apr 2021 13:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:09:30

US3192486

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Have you been exposed to someone with 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)	24 Apr 2021 13:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:09:30

US3192486

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:09:30

US3192486

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:09:30

US3192486

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:09:30

US3192486

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:09:30

US3192486

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:09:30

US3192486

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:09:30

US3192486

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:09:30

US3192486

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:09:30

US3192486

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:09:30

US3192486

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:09:30

US3192486
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:09:30

US3192486

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:09:30

US3192486
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:09:30

US3192486
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:09:30

US3192486

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:09:30

US3192486

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:09:30

US3192486
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:09:30

US3192486
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:09:30

US3192486
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:09:30

US3192486

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:09:30

US3192486

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:09:30

US3192486

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:09:30

US3192486

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:09:30

US3192486

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:09:30
Data entry locked.	System	26 Aug 2020 16:08:28
User entered '26 Oct 2020 00:01'	System	26 Aug 2020 16:08:28

US3192486

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:09:30
Data entry locked.	System	26 Aug 2020 16:08:28
User entered '30 Oct 2020 23:59'	System	26 Aug 2020 16:08:28

US3192486
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:09:30
Data entry locked.	System	26 Aug 2020 16:08:28
User entered 'Day 71'	System	26 Aug 2020 16:08:28

US3192486

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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)	24 Apr 2021 13:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:09:30

US3192486

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Have you been exposed to someone with 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)	24 Apr 2021 13:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:09:30

US3192486

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:09:30

US3192486

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:09:30

US3192486

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:09:30

US3192486

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:09:30

US3192486
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:09:30

US3192486

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:09:30

US3192486

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:09:30

US3192486
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:09:30

US3192486
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12

Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:09:30

US3192486

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:09:30

US3192486
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:09:30

US3192486

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:09:30

US3192486

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:09:30

US3192486

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:09:30

US3192486

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:09:30

US3192486

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:09:30

US3192486

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:09:30

US3192486

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:09:30

US3192486

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:09:30

US3192486

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:09:30

US3192486

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:09:30

US3192486

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:09:30

US3192486

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:09:30

US3192486

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:09:30
Data entry locked.	System	26 Aug 2020 16:08:28
User entered '02 Nov 2020 00:01'	System	26 Aug 2020 16:08:28

US3192486

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:53:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:09:30
Data entry locked.	System	26 Aug 2020 16:08:28
User entered '06 Nov 2020 23:59'	System	26 Aug 2020 16:08:28

FDA-CBER-2022-1614-0415564

US3192486
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
Data entry locked.	System	26 Aug 2020 16:08:28
User entered 'Day 78'	System	26 Aug 2020 16:08:28

US3192486

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-11-11T13:06:10', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '972ceed8-ecde-4db1-ab0a-4cffe4eff546'	System	11 Nov 2020 20:06:39
User entered 'No (N)'	System	11 Nov 2020 20:06:39

US3192486

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-11-11T13:06:14', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '972ceed8-ecde-4db1-ab0a-4cffe4eff546'	System	11 Nov 2020 20:06:39
User entered 'No (N)'	System	11 Nov 2020 20:06:39

US3192486

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-11-11T13:06:34', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '972ceed8-ecde-4db1-ab0a-4cffe4eff546'	System	11 Nov 2020 20:06:39
User entered '11 Nov 2020 13:06:34'	System	11 Nov 2020 20:06:39

US3192486

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
Data entry locked.	System	26 Aug 2020 16:08:28
User entered '09 Nov 2020 00:01'	System	26 Aug 2020 16:08:28

Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:58:30
Data entry locked.	System	26 Aug 2020 16:08:28
User entered '13 Nov 2020 23:59'	System	26 Aug 2020 16:08:28

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '20 Nov 2020 00:01'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '24 Nov 2020 23:59'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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 (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-11-30T17:59:55', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '01b812e6-985d-45f9-94e0-7577011ede34'	System	01 Dec 2020 01:00:42
User entered 'No (N)'	System	01 Dec 2020 01:00:42

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Have you been exposed to someone with 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 (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-11-30T18:00:01', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '01b812e6-985d-45f9-94e0-7577011ede34'	System	01 Dec 2020 01:00:42
User entered 'No (N)'	System	01 Dec 2020 01:00:42

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7538A89D-7883-41A3-9491-9F40CD310651)', Time: '2020-11-30T18:00:36', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '01b812e6-985d-45f9-94e0-7577011ede34'	System	01 Dec 2020 01:00:42
User entered '30 Nov 2020 18:00:36'	System	01 Dec 2020 01:00:42

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '27 Nov 2020 00:01'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '01 Dec 2020 23:59'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '04 Dec 2020 00:01'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '08 Dec 2020 23:59'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '11 Dec 2020 00:01'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '15 Dec 2020 23:59'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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 (4886E698-542D-404C-B8FB-02C4895A9904)', Time: '2020-12-22T10:02:08', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '84bc29f2-7b61-43d4-a4cd-f6a8e1400dd7'	System	22 Dec 2020 17:02:27
User entered 'No (N)'	System	22 Dec 2020 17:02:27

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Have you been exposed to someone with 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 (4886E698-542D-404C-B8FB-02C4895A9904)', Time: '2020-12-22T10:02:12', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '84bc29f2-7b61-43d4-a4cd-f6a8e1400dd7'	System	22 Dec 2020 17:02:27
User entered 'No (N)'	System	22 Dec 2020 17:02:27

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4886E698-542D-404C-B8FB-02C4895A9904)', Time: '2020-12-22T10:02:22', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '84bc29f2-7b61-43d4-a4cd-f6a8e1400dd7'	System	22 Dec 2020 17:02:27
User entered '22 Dec 2020 10:02:22'	System	22 Dec 2020 17:02:27

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '18 Dec 2020 00:01'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '22 Dec 2020 23:59'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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 (4886E698-542D-404C-B8FB-02C4895A9904)', Time: '2020-12-28T20:12:47', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '10e5b548-88ab-4351-96ce-e19edaab496a'	System	29 Dec 2020 03:13:22
User entered 'No (N)'	System	29 Dec 2020 03:13:22

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Have you been exposed to someone with 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 (4886E698-542D-404C-B8FB-02C4895A9904)', Time: '2020-12-28T20:12:59', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '10e5b548-88ab-4351-96ce-e19edaab496a'	System	29 Dec 2020 03:13:22
User entered 'No (N)'	System	29 Dec 2020 03:13:22

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4886E698-542D-404C-B8FB-02C4895A9904)', Time: '2020-12-28T20:13:17', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '10e5b548-88ab-4351-96ce-e19edaab496a'	System	29 Dec 2020 03:13:22
User entered '28 Dec 2020 20:13:17'	System	29 Dec 2020 03:13:22

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '25 Dec 2020 00:01'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '29 Dec 2020 23:59'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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 (4886E698-542D-404C-B8FB-02C4895A9904)', Time: '2021-01-03T12:00:29', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: 'e9ed496c-c587-4687-893d-e2733dffedc0'	System	03 Jan 2021 19:00:42
User entered 'No (N)'	System	03 Jan 2021 19:00:42

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Have you been exposed to someone with 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 (4886E698-542D-404C-B8FB-02C4895A9904)', Time: '2021-01-03T12:00:33', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: 'e9ed496c-c587-4687-893d-e2733dffedc0'	System	03 Jan 2021 19:00:42
User entered 'No (N)'	System	03 Jan 2021 19:00:42

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4886E698-542D-404C-B8FB-02C4895A9904)', Time: '2021-01-03T12:00:38', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: 'e9ed496c-c587-4687-893d-e2733dffedc0'	System	03 Jan 2021 19:00:42
User entered '03 Jan 2021 12:00:38'	System	03 Jan 2021 19:00:42

FDA-CBER-2022-1614-0415601

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '01 Jan 2021 00:01'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '05 Jan 2021 23:59'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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 (4886E698-542D-404C-B8FB-02C4895A9904)', Time: '2021-01-08T07:12:51', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '985a4a30-235c-40d2-adc0-7c69ce0f835b'	System	08 Jan 2021 14:13:06
User entered 'No (N)'	System	08 Jan 2021 14:13:06

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Have you been exposed to someone with 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 (4886E698-542D-404C-B8FB-02C4895A9904)', Time: '2021-01-08T07:12:54', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '985a4a30-235c-40d2-adc0-7c69ce0f835b'	System	08 Jan 2021 14:13:06
User entered 'No (N)'	System	08 Jan 2021 14:13:06

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4886E698-542D-404C-B8FB-02C4895A9904)', Time: '2021-01-08T07:12:59', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '985a4a30-235c-40d2-adc0-7c69ce0f835b'	System	08 Jan 2021 14:13:06
User entered '08 Jan 2021 07:12:59'	System	08 Jan 2021 14:13:06

FDA-CBER-2022-1614-0415607

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '08 Jan 2021 00:01'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '12 Jan 2021 23:59'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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 (4886E698-542D-404C-B8FB-02C4895A9904)', Time: '2021-01-15T06:21:12', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '0cb4a6fa-5992-4480-8ce7-26de55997a0a'	System	15 Jan 2021 13:21:23
User entered 'No (N)'	System	15 Jan 2021 13:21:23

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Have you been exposed to someone with 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 (4886E698-542D-404C-B8FB-02C4895A9904)', Time: '2021-01-15T06:21:15', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '0cb4a6fa-5992-4480-8ce7-26de55997a0a'	System	15 Jan 2021 13:21:23
User entered 'No (N)'	System	15 Jan 2021 13:21:23

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4886E698-542D-404C-B8FB-02C4895A9904)', Time: '2021-01-15T06:21:19', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '0cb4a6fa-5992-4480-8ce7-26de55997a0a'	System	15 Jan 2021 13:21:23
User entered '15 Jan 2021 06:21:19'	System	15 Jan 2021 13:21:23

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '15 Jan 2021 00:01'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '19 Jan 2021 23:59'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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 (4886E698-542D-404C-B8FB-02C4895A9904)', Time: '2021-01-22T06:20:39', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '2799f200-596d-4659-9c82-df2a576f6cd8'	System	22 Jan 2021 13:20:52
User entered 'No (N)'	System	22 Jan 2021 13:20:52

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Have you been exposed to someone with 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 (4886E698-542D-404C-B8FB-02C4895A9904)', Time: '2021-01-22T06:20:45', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '2799f200-596d-4659-9c82-df2a576f6cd8'	System	22 Jan 2021 13:20:52
User entered 'No (N)'	System	22 Jan 2021 13:20:52

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4886E698-542D-404C-B8FB-02C4895A9904)', Time: '2021-01-22T06:20:49', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '2799f200-596d-4659-9c82-df2a576f6cd8'	System	22 Jan 2021 13:20:52
User entered '22 Jan 2021 06:20:49'	System	22 Jan 2021 13:20:52

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '22 Jan 2021 00:01'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '26 Jan 2021 23:59'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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 (4886E698-542D-404C-B8FB-02C4895A9904)', Time: '2021-02-02T12:17:32', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: 'b38c3c99-143b-45a8-9061-3653f2a39b48'	System	02 Feb 2021 19:17:44
User entered 'No (N)'	System	02 Feb 2021 19:17:44

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Have you been exposed to someone with 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 (4886E698-542D-404C-B8FB-02C4895A9904)', Time: '2021-02-02T12:17:35', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: 'b38c3c99-143b-45a8-9061-3653f2a39b48'	System	02 Feb 2021 19:17:44
User entered 'No (N)'	System	02 Feb 2021 19:17:44

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4886E698-542D-404C-B8FB-02C4895A9904)', Time: '2021-02-02T12:17:41', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: 'b38c3c99-143b-45a8-9061-3653f2a39b48'	System	02 Feb 2021 19:17:44
User entered '02 Feb 2021 12:17:41'	System	02 Feb 2021 19:17:44

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '29 Jan 2021 00:01'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '02 Feb 2021 23:59'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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 (4886E698-542D-404C-B8FB-02C4895A9904)', Time: '2021-02-07T12:01:44', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: 'fce7752c-b8d4-43f2-8559-34e402cbbbdb'	System	07 Feb 2021 19:01:56
User entered 'No (N)'	System	07 Feb 2021 19:01:56

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Have you been exposed to someone with 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 (4886E698-542D-404C-B8FB-02C4895A9904)', Time: '2021-02-07T12:01:48', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: 'fce7752c-b8d4-43f2-8559-34e402cbbbdb'	System	07 Feb 2021 19:01:56
User entered 'No (N)'	System	07 Feb 2021 19:01:56

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4886E698-542D-404C-B8FB-02C4895A9904)', Time: '2021-02-07T12:01:53', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: 'fce7752c-b8d4-43f2-8559-34e402cbbbdb'	System	07 Feb 2021 19:01:56
User entered '07 Feb 2021 12:01:53'	System	07 Feb 2021 19:01:56

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '05 Feb 2021 00:01'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '09 Feb 2021 23:59'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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 (4886E698-542D-404C-B8FB-02C4895A9904)', Time: '2021-02-14T12:00:29', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: 'a65bc909-0d92-4c2a-8a98-ca20611ce5af'	System	14 Feb 2021 19:00:47
User entered 'No (N)'	System	14 Feb 2021 19:00:47

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Have you been exposed to someone with 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 (4886E698-542D-404C-B8FB-02C4895A9904)', Time: '2021-02-14T12:00:32', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: 'a65bc909-0d92-4c2a-8a98-ca20611ce5af'	System	14 Feb 2021 19:00:47
User entered 'No (N)'	System	14 Feb 2021 19:00:47

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4886E698-542D-404C-B8FB-02C4895A9904)', Time: '2021-02-14T12:00:36', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: 'a65bc909-0d92-4c2a-8a98-ca20611ce5af'	System	14 Feb 2021 19:00:47
User entered '14 Feb 2021 12:00:36'	System	14 Feb 2021 19:00:47

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '12 Feb 2021 00:01'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '16 Feb 2021 23:59'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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 (4886E698-542D-404C-B8FB-02C4895A9904)', Time: '2021-02-19T06:58:13', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: 'c87b059b-3b66-466a-8249-6e7c6dddf7b2'	System	19 Feb 2021 13:58:22
User entered 'No (N)'	System	19 Feb 2021 13:58:22

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Have you been exposed to someone with 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 (4886E698-542D-404C-B8FB-02C4895A9904)', Time: '2021-02-19T06:58:15', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: 'c87b059b-3b66-466a-8249-6e7c6dddf7b2'	System	19 Feb 2021 13:58:22
User entered 'No (N)'	System	19 Feb 2021 13:58:22

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4886E698-542D-404C-B8FB-02C4895A9904)', Time: '2021-02-19T06:58:18', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: 'c87b059b-3b66-466a-8249-6e7c6dddf7b2'	System	19 Feb 2021 13:58:22
User entered '19 Feb 2021 06:58:18'	System	19 Feb 2021 13:58:22

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '19 Feb 2021 00:01'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '23 Feb 2021 23:59'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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 (4886E698-542D-404C-B8FB-02C4895A9904)', Time: '2021-03-02T12:00:04-07:00', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '5d632e0c-5285-4305-9c41-0fad08c5697d'	System	02 Mar 2021 19:00:16
User entered 'No (N)'	System	02 Mar 2021 19:00:16

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Have you been exposed to someone with 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 (4886E698-542D-404C-B8FB-02C4895A9904)', Time: '2021-03-02T12:00:07-07:00', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '5d632e0c-5285-4305-9c41-0fad08c5697d'	System	02 Mar 2021 19:00:16
User entered 'No (N)'	System	02 Mar 2021 19:00:16

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4886E698-542D-404C-B8FB-02C4895A9904)', Time: '2021-03-02T12:00:11-07:00', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '5d632e0c-5285-4305-9c41-0fad08c5697d'	System	02 Mar 2021 19:00:16
User entered '02 Mar 2021 12:00:11'	System	02 Mar 2021 19:00:16

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '26 Feb 2021 00:01'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '02 Mar 2021 23:59'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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 (4886E698-542D-404C-B8FB-02C4895A9904)', Time: '2021-03-07T16:55:29-07:00', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '3dfa9684-c5fa-4687-8a7a-e82b1711ec54'	System	14 Mar 2021 19:36:10
User entered 'No (N)'	System	14 Mar 2021 19:36:10

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Have you been exposed to someone with 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 (4886E698-542D-404C-B8FB-02C4895A9904)', Time: '2021-03-07T16:55:32-07:00', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '3dfa9684-c5fa-4687-8a7a-e82b1711ec54'	System	14 Mar 2021 19:36:10
User entered 'No (N)'	System	14 Mar 2021 19:36:10

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4886E698-542D-404C-B8FB-02C4895A9904)', Time: '2021-03-07T16:55:35-07:00', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '3dfa9684-c5fa-4687-8a7a-e82b1711ec54'	System	14 Mar 2021 19:36:10
User entered '07 Mar 2021 16:55:35'	System	14 Mar 2021 19:36:10

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '05 Mar 2021 00:01'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '09 Mar 2021 23:59'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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 (4886E698-542D-404C-B8FB-02C4895A9904)', Time: '2021-03-14T12:36:05-07:00', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '82987fe3-dec8-42aa-9a2c-8f312a6f82a8'	System	14 Mar 2021 19:36:14
User entered 'No (N)'	System	14 Mar 2021 19:36:14

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Have you been exposed to someone with 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 (4886E698-542D-404C-B8FB-02C4895A9904)', Time: '2021-03-14T12:36:08-07:00', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '82987fe3-dec8-42aa-9a2c-8f312a6f82a8'	System	14 Mar 2021 19:36:14
User entered 'No (N)'	System	14 Mar 2021 19:36:14

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4886E698-542D-404C-B8FB-02C4895A9904)', Time: '2021-03-14T12:36:12-07:00', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '82987fe3-dec8-42aa-9a2c-8f312a6f82a8'	System	14 Mar 2021 19:36:14
User entered '14 Mar 2021 12:36:12'	System	14 Mar 2021 19:36:14

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '12 Mar 2021 00:01'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '16 Mar 2021 23:59'	System	19 Nov 2020 18:09:30

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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 (4886E698-542D-404C-B8FB-02C4895A9904)', Time: '2021-03-21T12:00:31-07:00', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '2c1d9829-7aa5-4897-ab83-eac841f0fe85'	System	21 Mar 2021 19:00:45
User entered 'No (N)'	System	21 Mar 2021 19:00:45

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Have you been exposed to someone with 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 (4886E698-542D-404C-B8FB-02C4895A9904)', Time: '2021-03-21T12:00:33-07:00', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '2c1d9829-7aa5-4897-ab83-eac841f0fe85'	System	21 Mar 2021 19:00:45
User entered 'No (N)'	System	21 Mar 2021 19:00:45

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4886E698-542D-404C-B8FB-02C4895A9904)', Time: '2021-03-21T12:00:36-07:00', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '2c1d9829-7aa5-4897-ab83-eac841f0fe85'	System	21 Mar 2021 19:00:45
User entered '21 Mar 2021 12:00:36'	System	21 Mar 2021 19:00:45

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '19 Mar 2021 00:01'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '23 Mar 2021 23:59'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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 (4886E698-542D-404C-B8FB-02C4895A9904)', Time: '2021-03-26T09:25:23-07:00', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: 'be9d5add-3015-407e-8420-97d50c30dd67'	System	26 Mar 2021 16:28:31
User entered 'No (N)'	System	26 Mar 2021 16:28:31

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Have you been exposed to someone with 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 (4886E698-542D-404C-B8FB-02C4895A9904)', Time: '2021-03-26T09:25:26-07:00', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: 'be9d5add-3015-407e-8420-97d50c30dd67'	System	26 Mar 2021 16:28:31
User entered 'No (N)'	System	26 Mar 2021 16:28:31

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4886E698-542D-404C-B8FB-02C4895A9904)', Time: '2021-03-26T09:25:30-07:00', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: 'be9d5add-3015-407e-8420-97d50c30dd67'	System	26 Mar 2021 16:28:31
User entered '26 Mar 2021 09:25:30'	System	26 Mar 2021 16:28:31

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '26 Mar 2021 00:01'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '30 Mar 2021 23:59'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '02 Apr 2021 00:01'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '06 Apr 2021 23:59'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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 (4886E698-542D-404C-B8FB-02C4895A9904)', Time: '2021-04-09T06:21:40-07:00', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '7b3b8e19-5856-4cbe-9463-5fafd2f9f698'	System	09 Apr 2021 13:21:52
User entered 'No (N)'	System	09 Apr 2021 13:21:52

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12

Have you been exposed to someone with 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 (4886E698-542D-404C-B8FB-02C4895A9904)', Time: '2021-04-09T06:21:43-07:00', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '7b3b8e19-5856-4cbe-9463-5fafd2f9f698'	System	09 Apr 2021 13:21:52
User entered 'No (N)'	System	09 Apr 2021 13:21:52

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4886E698-542D-404C-B8FB-02C4895A9904)', Time: '2021-04-09T06:21:48-07:00', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '7b3b8e19-5856-4cbe-9463-5fafd2f9f698'	System	09 Apr 2021 13:21:52
User entered '09 Apr 2021 06:21:48'	System	09 Apr 2021 13:21:52

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '09 Apr 2021 00:01'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '13 Apr 2021 23:59'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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 (4886E698-542D-404C-B8FB-02C4895A9904)', Time: '2021-04-18T12:22:57-07:00', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: 'b43dc4ca-df3e-47c1-aae2-84df83a45440'	System	18 Apr 2021 19:23:08
User entered 'No (N)'	System	18 Apr 2021 19:23:08

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Have you been exposed to someone with 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 (4886E698-542D-404C-B8FB-02C4895A9904)', Time: '2021-04-18T12:23:00-07:00', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: 'b43dc4ca-df3e-47c1-aae2-84df83a45440'	System	18 Apr 2021 19:23:08
User entered 'No (N)'	System	18 Apr 2021 19:23:08

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4886E698-542D-404C-B8FB-02C4895A9904)', Time: '2021-04-18T12:23:03-07:00', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: 'b43dc4ca-df3e-47c1-aae2-84df83a45440'	System	18 Apr 2021 19:23:08
User entered '18 Apr 2021 12:23:03'	System	18 Apr 2021 19:23:08

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '16 Apr 2021 00:01'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '20 Apr 2021 23:59'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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 (4886E698-542D-404C-B8FB-02C4895A9904)', Time: '2021-04-23T06:48:29-07:00', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: 'f520dee2-02f7-4498-a614-b9fab0fa2716'	System	23 Apr 2021 13:48:39
User entered 'No (N)'	System	23 Apr 2021 13:48:39

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Have you been exposed to someone with 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 (4886E698-542D-404C-B8FB-02C4895A9904)', Time: '2021-04-23T06:48:31-07:00', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: 'f520dee2-02f7-4498-a614-b9fab0fa2716'	System	23 Apr 2021 13:48:39
User entered 'No (N)'	System	23 Apr 2021 13:48:39

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4886E698-542D-404C-B8FB-02C4895A9904)', Time: '2021-04-23T06:48:35-07:00', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: 'f520dee2-02f7-4498-a614-b9fab0fa2716'	System	23 Apr 2021 13:48:39
User entered '23 Apr 2021 06:48:35'	System	23 Apr 2021 13:48:39

FDA-CBER-2022-1614-0415694

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '23 Apr 2021 00:01'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '27 Apr 2021 23:59'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

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 (4886E698-542D-404C-B8FB-02C4895A9904)', Time: '2021-05-02T12:30:32-07:00', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '18073c4e-3ecb-4d74-a7d7-b644abf0901d'	System	02 May 2021 19:30:40
User entered 'No (N)'	System	02 May 2021 19:30:40

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Have you been exposed to someone with 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 (4886E698-542D-404C-B8FB-02C4895A9904)', Time: '2021-05-02T12:30:35-07:00', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '18073c4e-3ecb-4d74-a7d7-b644abf0901d'	System	02 May 2021 19:30:40
User entered 'No (N)'	System	02 May 2021 19:30:40

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4886E698-542D-404C-B8FB-02C4895A9904)', Time: '2021-05-02T12:30:38-07:00', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '18073c4e-3ecb-4d74-a7d7-b644abf0901d'	System	02 May 2021 19:30:40
User entered '02 May 2021 12:30:38'	System	02 May 2021 19:30:40

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '30 Apr 2021 00:01'	System	19 Nov 2020 18:09:30

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '04 May 2021 23:59'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '07 May 2021 00:01'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '11 May 2021 23:59'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '14 May 2021 00:01'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '18 May 2021 23:59'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '21 May 2021 00:01'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '25 May 2021 23:59'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '28 May 2021 00:01'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '01 Jun 2021 23:59'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '04 Jun 2021 00:01'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '08 Jun 2021 23:59'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '11 Jun 2021 00:01'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '15 Jun 2021 23:59'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '18 Jun 2021 00:01'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '22 Jun 2021 23:59'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '25 Jun 2021 00:01'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '29 Jun 2021 23:59'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '02 Jul 2021 00:01'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '06 Jul 2021 23:59'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '09 Jul 2021 00:01'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '13 Jul 2021 23:59'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '16 Jul 2021 00:01'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '20 Jul 2021 23:59'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '23 Jul 2021 00:01'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '27 Jul 2021 23:59'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '30 Jul 2021 00:01'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '03 Aug 2021 23:59'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '06 Aug 2021 00:01'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '10 Aug 2021 23:59'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '13 Aug 2021 00:01'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '17 Aug 2021 23:59'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '20 Aug 2021 00:01'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '24 Aug 2021 23:59'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '27 Aug 2021 00:01'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '31 Aug 2021 23:59'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '03 Sep 2021 00:01'	System	19 Nov 2020 18:09:30

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '07 Sep 2021 23:59'	System	19 Nov 2020 18:09:30

FDA-CBER-2022-1614-0415756

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 18:09:30

FDA-CBER-2022-1614-0415757

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '10 Sep 2021 00:01'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '14 Sep 2021 23:59'	System	19 Nov 2020 18:09:30

FDA-CBER-2022-1614-0415759

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '17 Sep 2021 00:01'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '21 Sep 2021 23:59'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 18:09:30

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '24 Sep 2021 00:01'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '28 Sep 2021 23:59'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '01 Oct 2021 00:01'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '05 Oct 2021 23:59'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '08 Oct 2021 00:01'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '12 Oct 2021 23:59'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '15 Oct 2021 00:01'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '19 Oct 2021 23:59'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '22 Oct 2021 00:01'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '26 Oct 2021 23:59'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '29 Oct 2021 00:01'	System	19 Nov 2020 18:09:30

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '02 Nov 2021 23:59'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '05 Nov 2021 00:01'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '09 Nov 2021 23:59'	System	19 Nov 2020 18:09:30

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '12 Nov 2021 00:01'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '16 Nov 2021 23:59'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '19 Nov 2021 00:01'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '23 Nov 2021 23:59'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '26 Nov 2021 00:01'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '30 Nov 2021 23:59'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '03 Dec 2021 00:01'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '07 Dec 2021 23:59'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '10 Dec 2021 00:01'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '14 Dec 2021 23:59'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '17 Dec 2021 00:01'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '21 Dec 2021 23:59'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '24 Dec 2021 00:01'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '28 Dec 2021 23:59'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '31 Dec 2021 00:01'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '04 Jan 2022 23:59'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '07 Jan 2022 00:01'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '11 Jan 2022 23:59'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '14 Jan 2022 00:01'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '18 Jan 2022 23:59'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '21 Jan 2022 00:01'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '25 Jan 2022 23:59'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '28 Jan 2022 00:01'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '01 Feb 2022 23:59'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '04 Feb 2022 00:01'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '08 Feb 2022 23:59'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '11 Feb 2022 00:01'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '15 Feb 2022 23:59'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '18 Feb 2022 00:01'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '22 Feb 2022 23:59'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '25 Feb 2022 00:01'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '01 Mar 2022 23:59'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '04 Mar 2022 00:01'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '08 Mar 2022 23:59'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '11 Mar 2022 00:01'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '15 Mar 2022 23:59'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '18 Mar 2022 00:01'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '22 Mar 2022 23:59'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '25 Mar 2022 00:01'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '29 Mar 2022 23:59'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '01 Apr 2022 00:01'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '05 Apr 2022 23:59'	System	19 Nov 2020 18:09:30

FDA-CBER-2022-1614-0415846

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '08 Apr 2022 00:01'	System	19 Nov 2020 18:09:30

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '12 Apr 2022 23:59'	System	19 Nov 2020 18:09:30

FDA-CBER-2022-1614-0415849

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '15 Apr 2022 00:01'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '19 Apr 2022 23:59'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '22 Apr 2022 00:01'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '26 Apr 2022 23:59'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '29 Apr 2022 00:01'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '03 May 2022 23:59'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '06 May 2022 00:01'	System	19 Nov 2020 18:09:30

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '10 May 2022 23:59'	System	19 Nov 2020 18:09:30

FDA-CBER-2022-1614-0415861

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '13 May 2022 00:01'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '17 May 2022 23:59'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '20 May 2022 00:01'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '24 May 2022 23:59'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '27 May 2022 00:01'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '31 May 2022 23:59'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '03 Jun 2022 00:01'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '07 Jun 2022 23:59'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '10 Jun 2022 00:01'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '14 Jun 2022 23:59'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '17 Jun 2022 00:01'	System	19 Nov 2020 18:09:30

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '21 Jun 2022 23:59'	System	19 Nov 2020 18:09:30

FDA-CBER-2022-1614-0415879

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '24 Jun 2022 00:01'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '28 Jun 2022 23:59'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '01 Jul 2022 00:01'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '05 Jul 2022 23:59'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '08 Jul 2022 00:01'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '12 Jul 2022 23:59'	System	19 Nov 2020 18:09:30

FDA-CBER-2022-1614-0415888

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '15 Jul 2022 00:01'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '19 Jul 2022 23:59'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '22 Jul 2022 00:01'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '26 Jul 2022 23:59'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '29 Jul 2022 00:01'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '02 Aug 2022 23:59'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '05 Aug 2022 00:01'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '09 Aug 2022 23:59'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '12 Aug 2022 00:01'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '16 Aug 2022 23:59'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '19 Aug 2022 00:01'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '23 Aug 2022 23:59'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '26 Aug 2022 00:01'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '30 Aug 2022 23:59'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '02 Sep 2022 00:01'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '06 Sep 2022 23:59'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '09 Sep 2022 00:01'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '13 Sep 2022 23:59'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '16 Sep 2022 00:01'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '20 Sep 2022 23:59'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '23 Sep 2022 00:01'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '27 Sep 2022 23:59'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '30 Sep 2022 00:01'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '04 Oct 2022 23:59'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '07 Oct 2022 00:01'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '11 Oct 2022 23:59'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '14 Oct 2022 00:01'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '18 Oct 2022 23:59'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '21 Oct 2022 00:01'	System	19 Nov 2020 18:09:30

Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '25 Oct 2022 23:59'	System	19 Nov 2020 18:09:30

US3192486
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:43:12
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '28 Oct 2022 00:01'	System	19 Nov 2020 18:09:30

US3192486

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:12

Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:09:30
Amendment Manager: User entered '01 Nov 2022 23:59'	System	19 Nov 2020 18:09:30

US3192486

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:43:12

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 13:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4886E698-542D-404C-B8FB-02C4895A9904)', Time: '2021-03-21T12:00:55-07:00', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '17a4d857-1c60-4a7a-87aa-9954d0218bab'	System	21 Mar 2021 19:01:10
User entered 'No (N)'	System	21 Mar 2021 19:01:10

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:43:12

Date & Time of Submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:53:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4886E698-542D-404C-B8FB-02C4895A9904)', Time: '2021-03-21T12:01:00-07:00', User OID: 'PatientReportedOutcome (US3192486)', ODM File OID: '17a4d857-1c60-4a7a-87aa-9954d0218bab'	System	21 Mar 2021 19:01:10
User entered '21 Mar 2021 12:01:00'	System	21 Mar 2021 19:01:10

US3192486
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:43:12

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	09 Mar 2021 17:23:38
User entered 'Yes (Y)'	Amanda Hermosillo (b) (4)	20 Nov 2020 17:49:26

US3192486

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:12

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	09 Mar 2021 17:23:38
User entered '19 Nov 2020'	Amanda Hermosillo (b) (4)	20 Nov 2020 17:49:26

US3192486
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:43:12

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	09 Mar 2021 17:23:38
User entered 'Contact Made (CONTACT MADE)'	Amanda Hermosillo (b) (4)	20 Nov 2020 17:49:26

US3192486
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:43:12
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	09 Mar 2021 17:23:38
User entered empty.	Amanda Hermosillo (b) (4)	20 Nov 2020 17:49:26

US3192486

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:43:12

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	09 Mar 2021 17:23:38
User entered 'Yes (Y)'	Amanda Hermosillo (b) (4)	20 Nov 2020 17:49:29

US3192486
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:43:12
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:51:07
User entered '1'	System	20 Nov 2020 17:49:29

US3192486
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:43:12

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:52:53
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Dec 2020 22:14:23

US3192486

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:12

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:52:53
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
User entered '22 Dec 2020'	(b) (4), (b) (6)	22 Dec 2020 22:14:23

US3192486

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:12

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:52:53
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	22 Dec 2020 22:14:23

US3192486

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:12

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:52:53
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 22:14:23

US3192486

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:43:12

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:52:53
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Dec 2020 22:14:30

US3192486

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:43:12

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:52:53
User entered '1'	System	22 Dec 2020 22:14:30

US3192486
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:43:12

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:52:53
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'Yes (Y)'	Damaris Atondo (b) (4) (b) (4)	30 Jan 2021 21:34:41

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:52:53
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered '22 Jan 2021'	Damaris Atondo (b) (4) (b) (4)	30 Jan 2021 21:34:41

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Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:12

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:52:53
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'Contact Made (CONTACT MADE)'	Damaris Atondo (b) (4) (b) (4)	30 Jan 2021 21:34:41

US3192486

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:12

Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:52:53
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered empty.	Damaris Atondo (b) (4) (b) (4)	30 Jan 2021 21:34:41

US3192486

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:43:12

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:52:53
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'Yes (Y)'	Damaris Atondo (b) (4) (b) (4)	30 Jan 2021 21:34:55

US3192486

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:43:12

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:52:53
User entered '1'	System	30 Jan 2021 21:34:55

US3192486
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:43:12

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:52:53
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:38:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Feb 2021 21:45:25

Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:52:53
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:38:09
User entered '23 Feb 2021'	(b) (4), (b) (6)	23 Feb 2021 21:45:25

Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:52:53
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:38:09
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	23 Feb 2021 21:45:25

FDA-CBER-2022-1614-0415959

US3192486
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:43:12
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:52:53
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:38:09
User entered empty.	(b) (4), (b) (6)	23 Feb 2021 21:45:25

US3192486

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:43:12

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:52:53
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Feb 2021 21:45:30

US3192486

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:43:12

Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:52:53
User entered '1'	System	23 Feb 2021 21:45:30

US3192486
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:43:12

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:38:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Mar 2021 16:09:35

US3192486
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:43:12

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:38:09
User entered '12 Mar 2021'	(b) (4), (b) (6)	12 Mar 2021 16:09:35

US3192486

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:38:09
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	12 Mar 2021 16:09:35

US3192486
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:43:12
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User entered 'VISIT4'	System	12 Mar 2021 16:09:35

US3192486

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:12

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:38:09
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	01 Apr 2021 16:19:53

Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:38:09
User entered '12 Mar 2021'	Yvonne De Los Reyes (b) (4)	01 Apr 2021 16:19:53

US3192486
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:38:09
User entered '08:25'	Yvonne De Los Reyes (b) (4)	01 Apr 2021 16:19:53

US3192486

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:12

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User entered '12 Mar 2021 08:25'	System	01 Apr 2021 16:19:53

US3192486
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:43:12

Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:38:09
User entered '98.4' F	Yvonne De Los Reyes (b) (4)	01 Apr 2021 16:19:53

US3192486

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:12

Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:38:09
User entered 'Oral (Oral)'	Yvonne De Los Reyes (b) (4)	01 Apr 2021 16:19:53

US3192486
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:43:12
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:38:09
User entered empty.	Yvonne De Los Reyes (b) (4)	01 Apr 2021 16:19:53

US3192486
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:43:12

Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:38:09
User entered '64'	Yvonne De Los Reyes (b) (4)	01 Apr 2021 16:19:53

US3192486
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:43:12
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User entered 'bpm'	System	01 Apr 2021 16:19:53

US3192486
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:43:12

Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:38:09
User entered '12'	Yvonne De Los Reyes (b) (4)	01 Apr 2021 16:19:53

Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User entered 'breaths/min'	System	01 Apr 2021 16:19:53

US3192486
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:43:12

Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:38:09
User entered '100'	Yvonne De Los Reyes (b) (4)	01 Apr 2021 16:19:53

Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:43:12
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User entered 'mmHg'	System	01 Apr 2021 16:19:53

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US3192486

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:12

Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:38:09
User entered '64'	Yvonne De Los Reyes (b) (4)	01 Apr 2021 16:19:53

US3192486
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:43:12
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User entered 'mmHg'	System	01 Apr 2021 16:19:53

US3192486
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:43:12

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36

US3192486

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:12

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36

US3192486

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:43:12

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:38:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Mar 2021 16:09:43

US3192486

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:43:12

Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:38:09
User entered '12 Mar 2021'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 16:09:43

US3192486

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:43:12

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:38:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Mar 2021 16:10:05

US3192486

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:43:12

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:38:09
User entered '12 Mar 2021'	(b) (4), (b) (6)	12 Mar 2021 16:10:05

US3192486

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:38:09
User entered '08:48'	(b) (4), (b) (6)	12 Mar 2021 16:10:05

US3192486

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:43:12

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User entered '12 Mar 2021 08:48'	System	12 Mar 2021 16:10:05

US3192486

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:43:12

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:38:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Mar 2021 16:10:10

US3192486
Folder: Visit 4 Day 209 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:43:12
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:04:36
User entered '1'	System	12 Mar 2021 16:10:10

US3192486

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

Form: Visit Date

Generated On: 09 Jun 2021 15:43:12

Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:57:21
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'Yes (Y)'	Saysamone Banks (b) (4) (b) (4)	27 Jan 2021 00:02:18

US3192486

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

Form: Visit Date

Generated On: 09 Jun 2021 15:43:12

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:57:21
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered '26 Jan 2021'	Saysamone Banks (b) (4) (b) (4)	27 Jan 2021 00:02:18

US3192486

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

Form: Visit Date

Generated On: 09 Jun 2021 15:43:12

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 10:57:21
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'Clinic (Clinic)'	Saysamone Banks (b) (4) (b) (4)	27 Jan 2021 00:02:18

US3192486

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

Form: Visit Date

Generated On: 09 Jun 2021 15:43:12

Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:57:21
User entered 'UNBLND_DECIDE'	System	27 Jan 2021 00:02:18

US3192486

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

Form: Unblinding

Generated On: 09 Jun 2021 15:43:12

Date of updated informed consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:57:21
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered '26 Jan 2021'	Saysamone Banks (b) (4) (b) (4)	27 Jan 2021 00:02:49

US3192486

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

Form: Unblinding

Generated On: 09 Jun 2021 15:43:12

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 10:57:21
User signature succeeded.	John McGettigan (b) (4) (b) (4)	12 Apr 2021 17:57:18
User entered '0'	Damaris Atondo (b) (4) (b) (4)	09 Apr 2021 20:18:46
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 14:00:11

US3192486

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

Form: Unblinding

Generated On: 09 Jun 2021 15:43:12

Was the participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:57:21
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'Yes (Y)'	Saysamone Banks (b) (4) (b) (4)	27 Jan 2021 00:02:49

US3192486

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

Form: Unblinding

Generated On: 09 Jun 2021 15:43:12

Under what version of the Protocol was the Participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:57:21
User closed query ' Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field. ' (Site from DM).		19 Apr 2021 14:57:12
User signature succeeded.	John McGettigan (b) (4) (b) (4)	12 Apr 2021 17:57:18
Query ' Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field. ' answered with 'updated' (Site from DM).	Damaris Atondo (b) (4) (b) (4)	09 Apr 2021 20:19:00
User entered 'Amendment 6 or later (Amendment 6 or later)'	Damaris Atondo (b) (4) (b) (4)	09 Apr 2021 20:18:46
User opened query ' Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field. ' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 18:28:50
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 14:00:11

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

Form: Unblinding

Generated On: 09 Jun 2021 15:43:12

Date of unblinding *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:57:21
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered '26 Jan 2021'	Saysamone Banks (b) (4) (b) (4)	27 Jan 2021 00:02:49

US3192486

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

Form: Unblinding

Generated On: 09 Jun 2021 15:43:12

Participant randomization assignment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:57:21
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'mRNA-1273 (mRNA-1273)'	Saysamone Banks (b) (4) (b) (4)	27 Jan 2021 00:02:49

US3192486

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

Form: Unblinding

Generated On: 09 Jun 2021 15:43:12

Actual Dose 1

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:57:21
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'mRNA-1273 (mRNA-1273)'	Saysamone Banks (b) (4) (b) (4)	27 Jan 2021 00:02:49

US3192486

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

Form: Unblinding

Generated On: 09 Jun 2021 15:43:12

Actual Dose 2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:57:21
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'mRNA-1273 (mRNA-1273)'	Saysamone Banks (b) (4) (b) (4)	27 Jan 2021 00:02:49

US3192486

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

Form: Unblinding

Generated On: 09 Jun 2021 15:43:12

Will participant receive mRNA-1273?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:57:21
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'No (N)'	Saysamone Banks (b) (4) (b) (4)	27 Jan 2021 00:02:49

US3192486

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

Form: Unblinding

Generated On: 09 Jun 2021 15:43:12

Placebo Only Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:57:21
User entered empty.	System	27 Jan 2021 00:02:49

Continuing with mRNA-1273

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:57:21
User entered empty.	System	27 Jan 2021 00:02:49

FDA-CBER-2022-1614-0416006

US3192486

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:43:12

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:57:21
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'Yes (Y)'	Saysamone Banks (b) (4) (b) (4)	27 Jan 2021 00:03:37

US3192486

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:43:12

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:57:21
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered '26 Jan 2021'	Saysamone Banks (b) (4) (b) (4)	27 Jan 2021 00:03:37

US3192486

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:57:21
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered '15:11'	Saysamone Banks (b) (4) (b) (4)	27 Jan 2021 00:03:37

US3192486

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:43:12

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:57:21
User entered '26 Jan 2021 15:11'	System	27 Jan 2021 00:03:37

US3192486

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:43:12

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:57:21
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'Yes (Y)'	Saysamone Banks (b) (4) (b) (4)	27 Jan 2021 00:03:48

US3192486

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:43:12

Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:57:21
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered '26 Jan 2021'	Saysamone Banks (b) (4) (b) (4)	27 Jan 2021 00:03:48

US3192486

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:57:21
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered '14:28'	Saysamone Banks (b) (4) (b) (4)	27 Jan 2021 00:03:48

US3192486

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:43:12

Collection Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:57:21
User entered '26 Jan 2021 14:28'	System	27 Jan 2021 00:03:48

US3192486

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:43:12

Did the participant experience any adverse events?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:15:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	09 Mar 2021 16:25:15
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:16:32
User entered 'Yes (Y)' reason for change: New Information	Amanda Hermosillo (b) (4)	20 Nov 2020 17:49:40
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	12 Sep 2020 15:58:49

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:43:12

AEID

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:54:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:36:19
Reviewed for Safety.		23 Nov 2020 20:57:47
User entered 'USA-US097-2020-mRNA-1273-P301000006'	System	23 Nov 2020 20:57:28
User entered 'New'	(b) (4), (b) (6)	23 Nov 2020 20:57:28

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:43:12

Adverse event

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:54:12
User closed query 'Please consider spelling out what is meant by 'GI' in the adverse event term. Thank you.' (Site from CRA).	(b) (4), (b) (6)	30 Mar 2021 19:17:12
DataPoint Verified.		30 Mar 2021 19:17:10
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal haemorrhages NEC, HLT: Non-site specific gastrointestinal haemorrhages, PT: Gastrointestinal haemorrhage, LLT: Gastrointestinal bleed - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Mar 2021 22:02:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Mar 2021 22:02:32
Data point term sent to Coder	System	25 Mar 2021 22:01:33
Query 'Please consider spelling out what is meant by 'GI' in the adverse event term. Thank you.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	25 Mar 2021 22:01:12
Coding entries removed.		25 Mar 2021 22:01:03
User entered 'Gastrointestinal BLEED' reason for change: Data Entry Error		25 Mar 2021 22:01:03
User opened query 'Please consider spelling out what is meant by 'GI' in the adverse event term. Thank you.' (Site from CRA).		20 Jan 2021 19:19:38
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal haemorrhages NEC, HLT: Non-site specific gastrointestinal haemorrhages, PT: Gastrointestinal haemorrhage, LLT: GI bleed - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 20:16:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 20:16:15
Data point term sent to Coder	System	23 Nov 2020 18:12:18
Coding entries removed.	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 18:11:48
User entered 'GI BLEED' reason for change: Data Entry Error	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 18:11:48

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:43:12

Adverse event

Audit	User	Time (GMT)
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal haemorrhages NEC, HLT: Non-site specific gastrointestinal haemorrhages, PT: Gastrointestinal haemorrhage, LLT: GI bleed - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Nov 2020 22:32:24
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Nov 2020 22:32:24
Data point term sent to Coder	System	20 Nov 2020 17:53:23
User entered 'GI Bleed with colonoscopy'	Amanda Hermosillo (b) (4)	20 Nov 2020 17:53:06

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Folder: Adverse Events

Form: Adverse Events (1)

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Was this a medically-attended AE?

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:54:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:19:43
User entered 'Yes (Y)'	Amanda Hermosillo	20 Nov 2020 17:53:06
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:54:12
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:19:49
User entered 'No (N)'	Amanda Hermosillo (b) (4)	20 Nov 2020 17:53:06

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Folder: Adverse Events

Form: Adverse Events (1)

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Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:54:12
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:19:51
User entered 'No (N)'	Amanda Hermosillo (b) (4)	20 Nov 2020 17:53:06

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:43:12

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:54:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:19:54
User entered '02 Nov 2020'	Amanda Hermosillo (b) (4)	20 Nov 2020 17:53:06

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:43:12

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

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:54:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:20:00
User entered empty.	Amanda Hermosillo	20 Nov 2020 17:53:06
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:43:12

AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 17:53:06

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:43:12

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:54:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:20:02
User entered 'No (N)'	Amanda Hermosillo	20 Nov 2020 17:53:06
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:54:12
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:19:58
User entered '08 Nov 2020'	Amanda Hermosillo (b) (4)	20 Nov 2020 17:53:06

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:43:12

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

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:54:12
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:20:58
User entered empty.	Amanda Hermosillo (b) (4)	20 Nov 2020 17:53:06

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:43:12

AE End Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 17:53:06

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Folder: Adverse Events

Form: Adverse Events (1)

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Severity

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:54:12
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 19:17:19
User closed query 'Per source severity is 3-4. Please consider entering the worse case severity of 4. Thank you' (Site from CRA).		30 Mar 2021 19:17:17
Query 'Per source severity is 3-4. Please consider entering the worse case severity of 4. Thank you' answered with 'updated' (Site from CRA).		25 Mar 2021 21:59:52
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error		25 Mar 2021 21:59:43
User opened query 'Per source severity is 3-4. Please consider entering the worse case severity of 4. Thank you' (Site from CRA).		20 Jan 2021 19:21:48
User entered 'Grade 3/Severe (Grade 3/Severe)'	Amanda Hermosillo (b) (4)	20 Nov 2020 17:53:06

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:43:12

Is the adverse event serious?

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:54:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:21:51
User entered 'Yes (Y)' reason for change: Data Entry Error	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:59:42
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	23 Nov 2020 17:11:58
User entered 'No (N)' reason for change: Data Entry Error	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:11:58
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	20 Nov 2020 17:53:06
User entered 'Yes (Y)'	Amanda Hermosillo (b) (4)	20 Nov 2020 17:53:06

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Folder: Adverse Events
Form: Adverse Events (1)
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Death

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:54:12
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:21:57
User entered '0'	Amanda Hermosillo (b) (4)	20 Nov 2020 17:53:06

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Folder: Adverse Events

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Life threatening

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:54:12
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:21:58
User entered '0'	Amanda Hermosillo (b) (4)	20 Nov 2020 17:53:06

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Folder: Adverse Events

Form: Adverse Events (1)

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Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:54:12
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:22:01
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	23 Nov 2020 17:59:42
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).	System	23 Nov 2020 17:59:42
User entered '1' reason for change: Data Entry Error	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:59:42
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	20 Nov 2020 17:53:06
User entered '0'	Amanda Hermosillo (b) (4)	20 Nov 2020 17:53:06

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Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:54:12
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:22:03
User entered '02 Nov 2020'	Amanda Hermosillo (b) (4)	20 Nov 2020 17:53:06

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Folder: Adverse Events

Form: Adverse Events (1)

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Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:54:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:22:06
User entered '08 Nov 2020'	Amanda Hermosillo	20 Nov 2020 17:53:06
	(b) (4)	

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Admitted to ICU?

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:54:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:22:13
User entered 'No (N)'	Amanda Hermosillo (b) (4)	20 Nov 2020 17:53:06

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Number of Days in ICU

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:54:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:22:15
User entered empty.	Amanda Hermosillo	20 Nov 2020 17:53:06
	(b) (4)	

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Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:54:12
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:22:16
User entered '0'	Amanda Hermosillo (b) (4)	20 Nov 2020 17:53:06

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Folder: Adverse Events
Form: Adverse Events (1)
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Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:54:12
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:22:18
User entered '0'	Amanda Hermosillo (b) (4)	20 Nov 2020 17:53:06

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Form: Adverse Events (1)

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Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:54:12
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:22:19
User entered '0'	Amanda Hermosillo (b) (4)	20 Nov 2020 17:53:06

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Relationship to investigational product

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:54:12
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:22:22
User entered 'Not Related (NOT RELATED)'	Amanda Hermosillo (b) (4)	20 Nov 2020 17:53:06

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Relationship to Study Procedure

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:54:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:17:31
DataPoint Un-verified.		20 Jan 2021 19:23:34
DataPoint Verified.		20 Jan 2021 19:22:28
User entered 'Not Related (NOT RELATED)'	Amanda Hermosillo (b) (4)	20 Nov 2020 17:53:06

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Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:54:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 19:17:28
User closed query 'PV Query: As both scheduled doses of the study drug were already administered, please consider updating the action taken from no change to Not Applicable.' (Site from Safety).		28 Dec 2020 13:56:48
Query 'PV Query: As both scheduled doses of the study drug were already administered, please consider updating the action taken from no change to Not Applicable.' answered with 'Form updated. Awaiting for hospital records. ' (Site from Safety).	Tianna Young (b) (4) (b) (4)	24 Dec 2020 18:27:59
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Tianna Young (b) (4) (b) (4)	24 Dec 2020 18:27:39
User opened query 'PV Query: As both scheduled doses of the study drug were already administered, please consider updating the action taken from no change to Not Applicable.' (Site from Safety).	(b) (4), (b) (6)	30 Nov 2020 15:21:15
User entered 'None (NONE)'	Amanda Hermosillo (b) (4)	20 Nov 2020 17:53:06

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None

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:54:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:17:43
User closed query 'Per DM CLR: Other Action Taken = None, however there is a ConProc recorded that matches this AE during this timeframe. Please review and update AE eCRF as appropriate.' (Site from DM).		30 Mar 2021 05:46:11
Query 'Per DM CLR: Other Action Taken = None, however there is a ConProc recorded that matches this AE during this timeframe. Please review and update AE eCRF as appropriate.' answered with 'updated' (Site from DM).		25 Mar 2021 22:02:05
User entered '0' reason for change: Data Entry Error		25 Mar 2021 22:01:57
User opened query 'Per DM CLR: Other Action Taken = None, however there is a ConProc recorded that matches this AE during this timeframe. Please review and update AE eCRF as appropriate.' (Site from DM).		08 Jan 2021 07:06:16
User entered '1'	Amanda Hermosillo (b) (4)	20 Nov 2020 17:53:06

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Concomitant Medication

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:54:12
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 19:17:45
User entered '0'	Amanda Hermosillo (b) (4)	20 Nov 2020 17:53:06

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Concomitant Procedure

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:54:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:17:47
User entered '1' reason for change: Data Entry Error		25 Mar 2021 22:01:57
User entered '0'	Amanda Hermosillo (b) (4)	20 Nov 2020 17:53:06

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Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:43:12
Outcome

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:54:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Apr 2021 19:16:23
DataPoint Un-verified.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:20:05
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:20:05
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:24:02
Query 'PV Query: The event was reported as resolved with sequelae. Please provide the sequelae.' canceled (Site from Safety).		29 Dec 2020 16:51:28
User opened query 'PV Query: The event was reported as resolved with sequelae. Please provide the sequelae.' (Site from Safety).		30 Nov 2020 15:20:32
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Nov 2020 17:11:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Nov 2020 17:11:58
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)' reason for change: Data Entry Error	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:11:58
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Nov 2020 17:53:06
User entered empty.	Amanda Hermosillo (b) (4)	20 Nov 2020 17:53:06

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Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:43:12
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:54:12
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 19:16:41
User closed query 'Please confirm and list the condition which is the consequence of the GI Bleed. 'Colonoscopy' (per source) is the cause and not a consequence. Thanks' (Site from CRA).		03 Apr 2021 19:16:39
Query 'Please confirm and list the condition which is the consequence of the GI Bleed. 'Colonoscopy' (per source) is the cause and not a consequence. Thanks' answered with 'updated ' (Site from CRA).	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:20:14
User closed query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	System	03 Apr 2021 17:20:05
User opened query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	System	03 Apr 2021 17:18:12
User entered empty; reason for change Data Entry Error	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:18:12
DataPoint Un-verified.	(b) (4), (b) (6)	20 Jan 2021 19:36:06
User opened query 'Please confirm and list the condition which is the consequence of the GI Bleed. 'Colonoscopy' (per source) is the cause and not a consequence. Thanks' (Site from CRA).		20 Jan 2021 19:33:09
DataPoint Verified.		20 Jan 2021 19:24:04
User entered 'colonoscopy' reason for change: Data Entry Error	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 18:08:38
User entered 'chronic pancreatitis' reason for change: Data Entry Error	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:11:58
User entered empty.	Amanda Hermosillo (b) (4)	20 Nov 2020 17:53:06

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Narrative

Audit	User	Time (GMT)
User closed query 'PV Query: Please confirm if any treatment was given to the subject for the event of gastrointestinal bleed? If, yes then kindly specify. If no, then please state so.' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 15:08:02
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).		03 May 2021 15:07:59
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'records sent ' (Site from Safety).	Yvonne De Los Reyes (b) (4)	30 Apr 2021 20:03:00
Query 'PV Query: Please confirm if any treatment was given to the subject for the event of gastrointestinal bleed? If, yes then kindly specify. If no, then please state so.' answered with 'no treatment given' (Site from Safety).	Yvonne De Los Reyes (b) (4)	30 Apr 2021 20:02:52
User opened query 'PV Query: Please confirm if any treatment was given to the subject for the event of gastrointestinal bleed? If, yes then kindly specify. If no, then please state so.' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 21:00:38
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).		12 Apr 2021 21:00:31
User closed query 'Per DM CLR: SAE Narrative = SUBJECT WENT IN FOR SCHEDULED COLONOSCOPY AND ENDOSCOPY. However, these were not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).		05 Apr 2021 20:30:09
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).		05 Apr 2021 13:33:20

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Narrative

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	05 Apr 2021 13:33:16
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).		05 Apr 2021 13:33:12
User closed query 'PV Query: Please confirm if deep vein thrombosis is considered medical history (prior to start of study). If considered MH, please add to MH eCRF. If deep vein thrombosis is a new finding, please assess whether it meets criteria for separate AE/SAE reporting.' (Site from Safety).		05 Apr 2021 13:32:47
User closed query 'PV Query: Please confirm if pulmonary embolism is considered medical history (prior to start of study). If considered MH, please add to MH eCRF. If pulmonary embolism is a new finding, please assess whether it meets criteria for separate AE/SAE reporting.' (Site from Safety).		05 Apr 2021 13:32:42
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:54:12
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 19:16:55
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'diagnostic laboratory results available' (Site from Safety).	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:19:03
Query 'PV Query: Please confirm if deep vein thrombosis is considered medical history (prior to start of study). If considered MH, please add to MH eCRF. If deep vein thrombosis is a new finding, please assess whether it meets criteria for separate AE/SAE reporting.' answered with 'reported as AE' (Site from Safety).	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:17:34

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Generated On: 09 Jun 2021 15:43:12

Narrative

Audit	User	Time (GMT)
Query 'PV Query: Please confirm if pulmonary embolism is considered medical history (prior to start of study). If considered MH, please add to MH eCRF. If pulmonary embolism is a new finding, please assess whether it meets criteria for separate AE/SAE reporting.' answered with 'reported as AE ' (Site from Safety).	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:17:24
Query 'Per DM CLR: SAE Narrative = SUBJECT WENT IN FOR SCHEDULED COLONOSCOPY AND ENDOSCOPY. However, these were not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'updated ' (Site from DM).	Yvonne De Los Reyes (b) (4)	03 Apr 2021 16:49:13
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'updated ' (Site from Safety).	Yvonne De Los Reyes (b) (4)	03 Apr 2021 16:49:05
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'covid-19 test not done ' (Site from Safety).	Yvonne De Los Reyes (b) (4)	03 Apr 2021 16:48:47
User opened query 'Per DM CLR: SAE Narrative = SUBJECT WENT IN FOR SCHEDULED COLONOSCOPY AND ENDOSCOPY. However, these were 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)	08 Jan 2021 07:06:33
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).		29 Dec 2020 18:41:25

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Generated On: 09 Jun 2021 15:43:12
Narrative

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	29 Dec 2020 18:40:11
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).		29 Dec 2020 18:40:04
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).		28 Dec 2020 13:57:39
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).		28 Dec 2020 13:57:10
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).		28 Dec 2020 13:56:57
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'Awaiting hospital records.' (Site from Safety).	Tianna Young (b) (4) (b) (4)	24 Dec 2020 18:37:24
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'Awaiting hospital records.' (Site from Safety).	Tianna Young (b) (4) (b) (4)	24 Dec 2020 18:37:05

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Folder: Adverse Events

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Generated On: 09 Jun 2021 15:43:12

Narrative

Audit	User	Time (GMT)
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'Awaiting hospital records. ' (Site from Safety).	Tianna Young (b) (4) (b) (4)	24 Dec 2020 18:36:59
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	30 Nov 2020 15:20:48
User opened query 'PV Query: Please confirm if deep vein thrombosis is considered medical history (prior to start of study). If considered MH, please add to MH eCRF. If deep vein thrombosis is a new finding, please assess whether it meets criteria for separate AE/SAE reporting.' (Site from Safety).		30 Nov 2020 15:20:11
User opened query 'PV Query: Please confirm if pulmonary embolism is considered medical history (prior to start of study). If considered MH, please add to MH eCRF. If pulmonary embolism is a new finding, please assess whether it meets criteria for separate AE/SAE reporting.' (Site from Safety).		30 Nov 2020 15:19:53
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).		30 Nov 2020 15:19:38
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).		30 Nov 2020 15:19:28
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	23 Nov 2020 18:06:46
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	23 Nov 2020 18:06:46

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Narrative

Audit	User	Time (GMT)
User entered 'Subject went in for scheduled colonoscopy and endoscopy were it was noted his legs were swollen and he was given heparin which made him have the GI bleed from the colonoscopy.' reason for change: Data Entry Error	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 18:06:46
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	23 Nov 2020 17:59:42
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	23 Nov 2020 17:11:58
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	23 Nov 2020 17:11:58
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	20 Nov 2020 17:53:06
User entered empty.	Amanda Hermosillo (b) (4)	20 Nov 2020 17:53:06

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Form: Adverse Events (1)

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Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '1'	System	23 Nov 2020 17:59:42
User entered '0'	System	23 Nov 2020 17:11:58
User entered '1'	System	20 Nov 2020 17:53:06

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Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	20 Nov 2020 17:53:06

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Folder: Adverse Events

Form: Adverse Events (1)

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Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	20 Nov 2020 17:53:06

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Folder: Adverse Events

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AEID

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:33:57
User entered 'USA-US097-2020-mRNA-1273-P301000006'		05 Apr 2021 13:33:53
DataPoint activated with code reason code Data required.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:13:40
DataPoint inactivated with code reason code Data not required.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 16:51:31

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:43:12

Adverse event

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Surgery/procedures are not to be recorded as Adverse Events. Please record the underlying medical condition/diagnosis and update the AE as appropriate. Please ensure the surgery/procedure is recorded on the Con Proc eCRF. ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 20:31:09
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:54:12
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 19:18:57
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Pulmonary vascular disorders, HLT: Pulmonary thrombotic and embolic conditions, PT: Pulmonary embolism, LLT: Pulmonary embolism - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Apr 2021 17:17:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Apr 2021 17:17:40
Data point term sent to Coder	System	03 Apr 2021 17:17:03
User closed query 'For coding purposes, STENT PLACEMENT PANCREAS is not codable as entered. Procedures are not captured as an Adverse Event. Please delete the term or provide the diagnosis or underlying condition that necessitated the surgery/procedure.' (Site from System).	System	03 Apr 2021 17:16:55
Query 'For coding purposes, STENT PLACEMENT PANCREAS is not codable as entered. Procedures are not captured as an Adverse Event. Please delete the term or provide the diagnosis or underlying condition that necessitated the surgery/procedure.' answered with 'corrected data ' (Site from System).	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:16:55
Query 'Per DM CLR: Surgery/procedures are not to be recorded as Adverse Events. Please record the underlying medical condition/diagnosis and update the AE as appropriate. Please ensure the surgery/procedure is recorded on the Con Proc eCRF. ' answered with 'corrected data' (Site from DM).	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:16:48
User entered 'PUlmonARY EMBOLISM' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:16:41
Data point term sent to Coder	System	03 Apr 2021 17:16:02
Coding entries removed.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:16:01

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Form: Adverse Events (2)

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Adverse event

Audit	User	Time (GMT)
User entered 'Pulomary Embolism' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:16:01
Data point term sent to Coder	System	03 Apr 2021 17:14:00
DataPoint activated with code reason code Data required.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:13:40
Data point term sent to Coder	System	03 Apr 2021 16:51:54
DataPoint inactivated with code reason code Data not required.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 16:51:31
User opened query 'For coding purposes, STENT PLACEMENT PANCREAS is not codable as entered. Procedures are not captured as an Adverse Event. Please delete the term or provide the diagnosis or underlying condition that necessitated the surgery/procedure.' (Site from System).	Coder Import (b) (4) (b) (4)	30 Mar 2021 18:22:01
Query 'For coding purposes, STENT PLACEMENT PANCREAS is not codable as entered. Procedures are not captured as an Adverse Event. Please delete the term or provide the diagnosis or underlying condition that necessitated the surgery/procedure.' canceled (Site from Coder).	(b) (4), (b) (6)	30 Mar 2021 14:25:41
User coded data point as SOC: Gastrointestinal disorders, HLGT: Exocrine pancreas conditions, HLT: Pancreatic disorders NEC, PT: Pancreatic disorder, LLT: Unspecified disease of pancreas - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Jan 2021 14:45:40
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Jan 2021 14:45:40
User opened query 'Per DM CLR: Surgery/procedures are not to be recorded as Adverse Events. Please record the underlying medical condition/diagnosis and update the AE as appropriate. Please ensure the surgery/procedure is recorded on the Con Proc eCRF. ' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 13:49:45
User opened query 'For coding purposes, STENT PLACEMENT PANCREAS is not codable as entered. Procedures are not captured as an Adverse Event. Please delete the term or provide the diagnosis or underlying condition that necessitated the surgery/procedure.' (Site from Coder).		29 Nov 2020 15:31:27

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Adverse event

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Pancreatic therapeutic procedures, PT: Pancreatic stent placement, LLT: Pancreatic stent placement - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 21:14:11
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 21:14:11
Data point term sent to Coder	System	23 Nov 2020 17:14:42
User entered 'stent placement pancreas'	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:14:42

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Form: Adverse Events (2)

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Was this a medically-attended AE?

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:54:12
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 19:19:00
DataPoint activated with code reason code Data required.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:13:40
DataPoint inactivated with code reason code Data not required.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 16:51:31
User entered 'Yes (Y)'	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:14:42

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Form: Adverse Events (2)

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Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:54:12
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 19:19:13
DataPoint activated with code reason code Data required.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:13:40
DataPoint inactivated with code reason code Data not required.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 16:51:31
User entered 'No (N)'	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:14:42

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Folder: Adverse Events

Form: Adverse Events (2)

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Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:54:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Apr 2021 19:19:14
DataPoint activated with code reason code Data required.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:13:40
DataPoint inactivated with code reason code Data not required.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 16:51:31
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Nov 2020 17:14:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Nov 2020 17:14:53
User entered 'No (N)' reason for change: Data Entry Error	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:14:53
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Nov 2020 17:14:42
User entered empty.	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:14:42

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:43:12

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:54:12
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 19:19:17
DataPoint activated with code reason code Data required.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:13:40
DataPoint inactivated with code reason code Data not required.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 16:51:31
User entered '2 Nov 2020'	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:14:42

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Form: Adverse Events (2)
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Start time *(00:00-23:59)*

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:54:12
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 19:19:19
DataPoint activated with code reason code Data required.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:13:40
DataPoint inactivated with code reason code Data not required.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 16:51:31
User entered empty.	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:14:42

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Form: Adverse Events (2)

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AE start date and time (derived)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:13:40
DataPoint inactivated with code reason code Data not required.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 16:51:31
User entered empty.	System	23 Nov 2020 17:14:42

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Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:43:12
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:25
User closed 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)	30 Apr 2021 15:48:34
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.' answered with 'updated' (Site from Safety).	Yvonne De Los Reyes (b) (4)	29 Apr 2021 23:41:17
DataPoint Un-verified.	Yvonne De Los Reyes (b) (4)	29 Apr 2021 23:39:55
Signature has been broken.	Yvonne De Los Reyes (b) (4)	29 Apr 2021 23:39:55
User entered 'No (N)' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	29 Apr 2021 23:39:55
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)	12 Apr 2021 21:02:23
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:54:12
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 19:19:21
User entered 'Yes (Y)' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:16:41
DataPoint activated with code reason code Data required.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:13:40
DataPoint inactivated with code reason code Data not required.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 16:51:31
User entered 'No (N)'	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:14:42

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Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:43:12
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:25
DataPoint Un-verified.	Yvonne De Los Reyes (b) (4)	29 Apr 2021 23:39:55
Signature has been broken.	Yvonne De Los Reyes (b) (4)	29 Apr 2021 23:39:55
User entered '08 Nov 2020' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	29 Apr 2021 23:39:55
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:54:12
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 19:19:24
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	03 Apr 2021 17:16:41
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	03 Apr 2021 17:16:41
User entered empty; reason for change Data Entry Error	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:16:41
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	03 Apr 2021 17:16:01
User entered '08 Nov 2020' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:16:01
DataPoint activated with code reason code Data required.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:13:40
DataPoint inactivated with code reason code Data not required.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 16:51:31
User entered '2 Nov 2020'	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:14:42

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Form: Adverse Events (2)

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

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:54:12
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 19:19:25
DataPoint activated with code reason code Data required.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:13:40
DataPoint inactivated with code reason code Data not required.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 16:51:31
User entered empty.	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:14:42

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Folder: Adverse Events

Form: Adverse Events (2)

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AE End Date and Time (derived)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:13:40
DataPoint inactivated with code reason code Data not required.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 16:51:31
User entered empty.	System	23 Nov 2020 17:14:42

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Severity

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:54:12
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 19:19:27
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:16:01
DataPoint activated with code reason code Data required.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:13:40
DataPoint inactivated with code reason code Data not required.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 16:51:31
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:14:42

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Is the adverse event serious?

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:54:12
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 19:19:28
User entered 'Yes (Y)' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:16:01
DataPoint activated with code reason code Data required.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:13:40
DataPoint inactivated with code reason code Data not required.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 16:51:31
User entered 'No (N)'	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:14:42

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Form: Adverse Events (2)

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Death

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:54:12
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 19:27:00
DataPoint activated with code reason code Data required.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:13:40
DataPoint inactivated with code reason code Data not required.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 16:51:31
User entered '0'	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:14:42

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Folder: Adverse Events

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Life threatening

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:54:12
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 19:27:00
DataPoint activated with code reason code Data required.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:13:40
DataPoint inactivated with code reason code Data not required.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 16:51:31
User entered '0'	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:14:42

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:43:12

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:54:12
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 19:27:00
User entered '1' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:16:01
DataPoint activated with code reason code Data required.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:13:40
DataPoint inactivated with code reason code Data not required.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 16:51:31
User entered '0'	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:14:42

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Folder: Adverse Events

Form: Adverse Events (2)

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Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:54:12
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 19:27:00
User entered '02 Nov 2020' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:16:01
DataPoint activated with code reason code Data required.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:13:40
DataPoint inactivated with code reason code Data not required.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 16:51:31
User entered empty.	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:14:42

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:43:12

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:54:12
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 19:27:00
User entered '08 Nov 2020' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:16:01
DataPoint activated with code reason code Data required.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:13:40
DataPoint inactivated with code reason code Data not required.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 16:51:31
User entered empty.	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:14:42

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:43:12

Admitted to ICU?

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:54:12
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 19:27:00
User entered 'Yes (Y)' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:16:01
DataPoint activated with code reason code Data required.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:13:40
DataPoint inactivated with code reason code Data not required.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 16:51:31
User entered empty.	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:14:42

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Form: Adverse Events (2)
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Number of Days in ICU

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:54:12
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 19:27:00
User entered '7' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:16:01
DataPoint activated with code reason code Data required.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:13:40
DataPoint inactivated with code reason code Data not required.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 16:51:31
User entered empty.	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:14:42

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:43:12

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:54:12
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 19:27:00
DataPoint activated with code reason code Data required.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:13:40
DataPoint inactivated with code reason code Data not required.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 16:51:31
User entered '0'	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:14:42

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:43:12

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:54:12
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 19:27:00
DataPoint activated with code reason code Data required.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:13:40
DataPoint inactivated with code reason code Data not required.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 16:51:31
User entered '0'	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:14:42

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:43:12

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:54:12
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 19:27:00
DataPoint activated with code reason code Data required.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:13:40
DataPoint inactivated with code reason code Data not required.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 16:51:31
User entered '0'	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:14:42

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:43:12

Relationship to investigational product

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:54:12
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 19:27:00
DataPoint activated with code reason code Data required.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:13:40
DataPoint inactivated with code reason code Data not required.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 16:51:31
User entered 'Not Related (NOT RELATED)'	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:14:42

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:43:12

Relationship to Study Procedure

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:54:12
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 19:27:00
DataPoint activated with code reason code Data required.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:13:40
DataPoint inactivated with code reason code Data not required.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 16:51:31
User entered 'Not Related (NOT RELATED)'	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:14:42

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:43:12

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:25
User closed query 'As the last dose of study drug was given on 23 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 15:48:39
Query 'As the last dose of study drug was given on 23 Sep 2020, please update the action taken with study drug from none to not applicable.' answered with 'updated' (Site from Safety).	Yvonne De Los Reyes (b) (4)	29 Apr 2021 23:40:07
DataPoint Un-verified.	Yvonne De Los Reyes (b) (4)	29 Apr 2021 23:39:55
Signature has been broken.	Yvonne De Los Reyes (b) (4)	29 Apr 2021 23:39:55
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	29 Apr 2021 23:39:55
User opened query 'As the last dose of study drug was given on 23 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 21:02:12
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:54:12
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 19:27:00
DataPoint activated with code reason code Data required.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:13:40
DataPoint inactivated with code reason code Data not required.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 16:51:31
User entered 'None (NONE)'	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:14:42

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:43:12

None

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:54:12
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 19:27:00
User entered '0' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:16:01
DataPoint activated with code reason code Data required.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:13:40
DataPoint inactivated with code reason code Data not required.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 16:51:31
User entered '1'	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:14:42

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:43:12

Concomitant Medication

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:54:12
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 19:27:00
User entered '1' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:16:01
DataPoint activated with code reason code Data required.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:13:40
DataPoint inactivated with code reason code Data not required.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 16:51:31
User entered '0'	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:14:42

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:43:12

Concomitant Procedure

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:54:12
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 19:27:00
DataPoint activated with code reason code Data required.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:13:40
DataPoint inactivated with code reason code Data not required.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 16:51:31
User entered '0'	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:14:42

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:43:12

Outcome

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:25
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 15:48:45
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'updated' (Site from Safety).	Yvonne De Los Reyes (b) (4)	29 Apr 2021 23:40:14
DataPoint Un-verified.	Yvonne De Los Reyes (b) (4)	29 Apr 2021 23:39:55
Signature has been broken.	Yvonne De Los Reyes (b) (4)	29 Apr 2021 23:39:55
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	29 Apr 2021 23:39:55
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 21:02:34
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:54:12
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 19:27:00
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:16:01
DataPoint activated with code reason code Data required.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:13:40
DataPoint inactivated with code reason code Data not required.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 16:51:31
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Nov 2020 17:14:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Nov 2020 17:14:53
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:14:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:43:12

Outcome

Audit	User	Time (GMT)
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Nov 2020 17:14:42
User entered empty.	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:14:42

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:43:12

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

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:54:12
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 19:27:00
DataPoint activated with code reason code Data required.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:13:40
DataPoint inactivated with code reason code Data not required.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 16:51:31
User entered empty.	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:14:42

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Folder: Adverse Events

Form: Adverse Events (2)

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Narrative

Audit	User	Time (GMT)
User closed query 'PV Query: Please clarify whether subject had any risk factors for DVT/PE (i.e. history of smoking, prolonged sitting/bed rest/immobilization, injury or surgery, or history of hypercoagulability disorder.)' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 15:08:16
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).		03 May 2021 15:08:14
Query 'PV Query: Please clarify whether subject had any risk factors for DVT/PE (i.e. history of smoking, prolonged sitting/bed rest/immobilization, injury or surgery, or history of hypercoagulability disorder.)' answered with 'per records, no history' (Site from Safety).	Yvonne De Los Reyes (b) (4)	30 Apr 2021 20:02:29
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'records sent' (Site from Safety).	Yvonne De Los Reyes (b) (4)	30 Apr 2021 20:02:12
User opened query 'PV Query: Please clarify whether subject had any risk factors for DVT/PE (i.e. history of smoking, prolonged sitting/bed rest/immobilization, injury or surgery, or history of hypercoagulability disorder.)' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 21:02:53
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).		12 Apr 2021 21:02:42
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:54:12
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 19:27:00
User entered 'Patient was diagnosed with pulmonary embolism during colonoscopy/endoscopy procedure.' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:16:01
DataPoint activated with code reason code Data required.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:13:40
DataPoint inactivated with code reason code Data not required.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 16:51:31
User entered empty.	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:14:42

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:43:12

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '1'	System	03 Apr 2021 17:16:01
DataPoint activated with code reason code Data required.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:13:40
DataPoint inactivated with code reason code Data not required.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 16:51:31
User entered '0'	System	23 Nov 2020 17:14:42

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:43:12

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:13:40
DataPoint inactivated with code reason code Data not required.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 16:51:31
User entered '1'	System	23 Nov 2020 17:14:42

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:43:12

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	03 Apr 2021 17:16:01
DataPoint activated with code reason code Data required.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:13:40
DataPoint inactivated with code reason code Data not required.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 16:51:31

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:43:12

AEID

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:34:30
User entered 'USA-US097-2020-mRNA-1273-P301000006'		05 Apr 2021 13:34:25

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:43:12

Adverse event

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:54:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Apr 2021 19:27:16
User coded data point as SOC: Vascular disorders, HLGT: Embolism and thrombosis, HLT: Peripheral embolism and thrombosis, PT: Deep vein thrombosis, LLT: Deep vein thrombosis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Apr 2021 16:54:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Apr 2021 16:54:28
Data point term sent to Coder	System	03 Apr 2021 16:53:55
Query 'For coding purposes, please split DEEP VEIN THROMBOSIS & PULMONARY EMBOLISM into two entries' canceled (Site from System).	Coder Import (b) (4) (b) (4)	03 Apr 2021 16:53:28
User coded data point as SOC: Vascular disorders, HLGT: Embolism and thrombosis, HLT: Peripheral embolism and thrombosis, PT: Deep vein thrombosis, LLT: Deep vein thrombosis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Apr 2021 16:53:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Apr 2021 16:53:27
Data point term sent to Coder	System	03 Apr 2021 16:52:54
Coding entries removed.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 16:52:00
User entered 'DEEP VEIN THROMBOSIS' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	03 Apr 2021 16:52:00
User opened query 'For coding purposes, please split DEEP VEIN THROMBOSIS & PULMONARY EMBOLISM into two entries' (Site from System).	Coder Import (b) (4) (b) (4)	30 Mar 2021 16:19:04
Query 'For coding purposes, please split DEEP VEIN THROMBOSIS & PULMONARY EMBOLISM into separate entries. 1. DEEP VEIN THROMBOSIS(Specify location) & 2. PULMONARY EMBOLISM' canceled (Site from Coder).	(b) (4), (b) (6)	30 Mar 2021 14:25:41
User opened query 'For coding purposes, please split DEEP VEIN THROMBOSIS & PULMONARY EMBOLISM into separate entries. 1. DEEP VEIN THROMBOSIS(Specify location) & 2. PULMONARY EMBOLISM' (Site from Coder).		28 Nov 2020 18:32:29

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:43:12

Adverse event

Audit	User	Time (GMT)
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Pulmonary vascular disorders, HLT: Pulmonary thrombotic and embolic conditions, PT: Pulmonary embolism, LLT: Pulmonary embolism - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 19:09:58
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 19:09:58
Data point term sent to Coder	System	23 Nov 2020 17:19:52
User entered 'Deep vein thrombosis & pulmonary embolism'	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:19:35

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:43:12

Was this a medically-attended AE?

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:54:12
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:43:11
User entered 'Yes (Y)'	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:19:35

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:43:12

Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:54:12
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:43:24
User entered 'No (N)'	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:19:35

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Form: Adverse Events (3)

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Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:54:12
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:43:27
User entered 'No (N)'	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:19:35

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:43:12

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:54:12
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:43:29
User entered '2 Nov 2020'	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:19:35

US3192486

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:43:12

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

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:54:12
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:43:32
User entered empty.	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:19:35

US3192486

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:43:12

AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 17:19:35

US3192486
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:43:12
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:25
User closed 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)	30 Apr 2021 15:49:01
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.' answered with 'updated ' (Site from Safety).	Yvonne De Los Reyes (b) (4)	29 Apr 2021 23:39:02
DataPoint Un-verified.	Yvonne De Los Reyes (b) (4)	29 Apr 2021 23:38:53
Signature has been broken.	Yvonne De Los Reyes (b) (4)	29 Apr 2021 23:38:53
User entered 'No (N)' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	29 Apr 2021 23:38:53
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)	12 Apr 2021 21:04:49
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing.' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 20:31:41
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:54:12
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing.' answered with 'ongoing' (Site from DM).	Yvonne De Los Reyes (b) (4)	03 Apr 2021 16:54:11
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:43:54
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing.' (Site from DM).		08 Jan 2021 07:07:03
User entered 'Yes (Y)'	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:19:35

US3192486
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:43:12
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:25
DataPoint Un-verified.	Yvonne De Los Reyes (b) (4)	29 Apr 2021 23:38:53
Signature has been broken.	Yvonne De Los Reyes (b) (4)	29 Apr 2021 23:38:53
User entered '08 Nov 2020' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	29 Apr 2021 23:38:53
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:54:12
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:43:57
User entered empty.	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:19:35

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:43:12

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

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:54:12
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:44:07
User entered empty.	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:19:35

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:43:12

AE End Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 17:19:35

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:43:12

Severity

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:54:12
User closed query 'Per source severity is 3-4. Please consider entering the worse case severity of 4. Thank you ' (Site from CRA).	(b) (4), (b) (6)	03 Apr 2021 19:27:33
DataPoint Verified.		03 Apr 2021 19:27:31
Query 'Per source severity is 3-4. Please consider entering the worse case severity of 4. Thank you ' answered with 'updated ' (Site from CRA).	Yvonne De Los Reyes (b) (4)	03 Apr 2021 16:54:17
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	03 Apr 2021 16:52:00
User opened query 'Per source severity is 3-4. Please consider entering the worse case severity of 4. Thank you ' (Site from CRA).	(b) (4), (b) (6)	20 Jan 2021 19:44:41
User entered 'Grade 3/Severe (Grade 3/Severe)'	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:19:35

US3192486
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:43:12
Is the adverse event serious?

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:54:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 19:27:36
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	03 Apr 2021 17:12:53
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	03 Apr 2021 17:12:25
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	03 Apr 2021 17:11:48
User closed query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).	System	03 Apr 2021 16:54:37
Query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' answered by data change (Site from System).	System	03 Apr 2021 16:54:37
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	03 Apr 2021 16:54:37
DataPoint Un-verified.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 16:54:37
User entered 'Yes (Y)' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	03 Apr 2021 16:54:37
User opened query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).	System	03 Apr 2021 16:52:00
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:44:45
User entered 'No (N)'	Saysamone Banks (b) (4)	23 Nov 2020 17:19:35
	(b) (4)	

US3192486
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:43:12
Death

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:54:12
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:45:02
User entered '0'	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:19:35

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:43:12

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:54:12
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:45:05
User entered '0'	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:19:35

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:43:12

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:54:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Apr 2021 19:27:54
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	03 Apr 2021 17:12:53
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).	System	03 Apr 2021 17:12:53
User entered '1' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:12:53
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	03 Apr 2021 17:12:25
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	03 Apr 2021 17:12:25
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System).	System	03 Apr 2021 17:12:25
User entered '0' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:12:25
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	03 Apr 2021 17:11:48
DataPoint Un-verified.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:11:48
User entered '1' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:11:48
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:45:07

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:43:12

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User entered '0'	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:19:35

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:43:12

Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:54:12
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 19:27:54
DataPoint Un-verified.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:11:48
User entered '02 Nov 2020' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:11:48
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:45:09
User entered empty.	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:19:35

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:43:12

Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:54:12
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 19:27:54
DataPoint Un-verified.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:11:48
User entered '08 Nov 2020' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:11:48
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:45:10
User entered empty.	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:19:35

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:43:12

Admitted to ICU?

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:54:12
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 19:27:54
DataPoint Un-verified.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:12:25
User entered 'Yes (Y)' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:12:25
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:45:12
User entered empty.	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:19:35

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:43:12

Number of Days in ICU

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	03 Apr 2021 23:54:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Apr 2021 19:27:54
User closed query 'Participant was not hospitalized or Admitted to ICU? is No however Number of Days in ICU has been provided. Please review and reconcile.' (Site from System).	System	03 Apr 2021 17:12:53
Query 'Participant was not hospitalized or Admitted to ICU? is No however Number of Days in ICU has been provided. Please review and reconcile.' answered by data change (Site from System).	System	03 Apr 2021 17:12:53
User opened query 'Participant was not hospitalized or Admitted to ICU? is No however Number of Days in ICU has been provided. Please review and reconcile.' (Site from System).	System	03 Apr 2021 17:12:25
DataPoint Un-verified.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:12:25
User entered '7' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:12:25
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:45:13
User entered empty.	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:19:35

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:43:12

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:54:12
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:45:15
User entered '0'	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:19:35

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:43:12

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:54:12
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:45:16
User entered '0'	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:19:35

US3192486
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:43:12
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:54:12
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:45:19
User entered '0'	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:19:35

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Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:43:12
Relationship to investigational product

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:54:12
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:45:30
User entered 'Not Related (NOT RELATED)'	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:19:35

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:43:12

Relationship to Study Procedure

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:54:12
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 19:27:54
User entered 'Not Related (NOT RELATED)'	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:19:35

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:43:12

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:25
User closed query 'PV Query: As the last dose of study drug was given on 23 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 15:49:07
Query 'PV Query: As the last dose of study drug was given on 23 Sep 2020, please update the action taken with study drug from none to not applicable.' answered with 'updated ' (Site from Safety).	Yvonne De Los Reyes (b) (4)	29 Apr 2021 23:39:10
DataPoint Un-verified.	Yvonne De Los Reyes (b) (4)	29 Apr 2021 23:38:53
Signature has been broken.	Yvonne De Los Reyes (b) (4)	29 Apr 2021 23:38:53
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	29 Apr 2021 23:38:53
User opened query 'PV Query: As the last dose of study drug was given on 23 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 21:05:02
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:54:12
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:45:48
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Nov 2020 17:19:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Nov 2020 17:19:42
User entered 'None (NONE)' reason for change: Data Entry Error	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:19:42
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Nov 2020 17:19:35
User entered empty.	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:19:35

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:43:12

None

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:54:12
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 19:27:54
DataPoint Un-verified.		20 Jan 2021 19:46:04
DataPoint Verified.		20 Jan 2021 19:45:50
User entered '0'	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:19:35

US3192486
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:43:12
Concomitant Medication

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:54:12
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 19:27:54
User entered '1'	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:19:35

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:43:12

Concomitant Procedure

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:54:12
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 19:27:54
User entered '0'	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:19:35

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:43:12

Outcome

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 20:43:25
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 15:49:09
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'updated ' (Site from Safety).	Yvonne De Los Reyes (b) (4)	29 Apr 2021 23:39:16
DataPoint Un-verified.	Yvonne De Los Reyes (b) (4)	29 Apr 2021 23:38:53
Signature has been broken.	Yvonne De Los Reyes (b) (4)	29 Apr 2021 23:38:53
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	29 Apr 2021 23:38:53
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 21:04:37
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:54:12
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:46:00
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:19:35

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

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:54:12
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:46:06
User entered empty.	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:19:35

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Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 15:43:12
Narrative

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 15:08:28
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'records sent' (Site from Safety).	Yvonne De Los Reyes (b) (4)	30 Apr 2021 20:02:03
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 21:04:25
User signature succeeded.	John McGettigan (b) (4) (b) (4)	03 Apr 2021 23:54:12
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 19:27:54
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	03 Apr 2021 17:11:48
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	03 Apr 2021 17:11:48
DataPoint Un-verified.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:11:48
User entered 'Patient was diagnosed with DVT during colonoscopy/endoscopy procedure.' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:11:48
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	03 Apr 2021 16:54:37
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:46:07
User entered empty.	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:19:35

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:43:12

Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '1'	System	03 Apr 2021 16:54:37
User entered '0'	System	23 Nov 2020 17:19:35

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:43:12

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	23 Nov 2020 17:19:35

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:43:12

Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	03 Apr 2021 17:12:25

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:15:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User closed query 'Per ETRTR: Please confirm whether any Medication was dosed during Hospitalization for SAE "GI Bleed". If provided, please ensure data entry within this folder, thanks.' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 03:07:42
Query 'Per ETRTR: Please confirm whether any Medication was dosed during Hospitalization for SAE "GI Bleed". If provided, please ensure data entry within this folder, thanks.' answered with 'its noted as a procedure ' (Site from CRA).	maggie Tono (b) (4) (b) (4)	31 Mar 2021 15:39:02
User opened query 'Per ETRTR: Please confirm whether any Medication was dosed during Hospitalization for SAE "GI Bleed". If provided, please ensure data entry within this folder, thanks.' (Site from CRA).	(b) (4), (b) (6)	07 Dec 2020 23:15:51
User entered 'Yes (Y)'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:19:33

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:43:12

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE SODIUM, PRODUCTSYNONYM: LEVOTHYROXIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 23:21:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 23:21:39
Data point term sent to Coder	System	18 Sep 2020 23:20:27
Coding entries removed.	Norma Barrientos (b) (4) (b) (4)	18 Sep 2020 23:20:19
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE SODIUM, PRODUCTSYNONYM: LEVOTHYROXIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Aug 2020 23:21:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Aug 2020 23:21:48
Data point term sent to Coder	System	29 Aug 2020 23:20:49
User entered 'Levothyroxin'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:20:27

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:43:12

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User closed query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 03:12:57
Query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' answered with 'not a prophylaxis criteria' (Site from DM).	maggie Tono (b) (4) (b) (4)	03 Nov 2020 20:58:27
User entered 'No (N)' reason for change: Data Entry Error	maggie Tono (b) (4) (b) (4)	03 Nov 2020 20:58:03
User opened query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 01:16:16
User entered 'Yes (Y)'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:20:27

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:43:12

Indication

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'HYPOTHYROIDISM' reason for change: Data Entry Error	Norma Barrientos (b) (4) (b) (4)	18 Sep 2020 23:20:19
User entered 'Hypothyroid'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:20:27

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:43:12

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered '150'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:20:27

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:43:12

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 03:16:18
Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' answered with 'updated' (Site from DM).	maggie Tono (b) (4) (b) (4)	03 Nov 2020 21:00:23
User entered 'ug (ug)' reason for change: Data Entry Error	maggie Tono (b) (4) (b) (4)	03 Nov 2020 21:00:16
User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 01:16:27
User entered 'mg (mg)'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:20:27

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:43:12

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered empty.	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:20:27

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:43:12

Frequency

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'once daily (QD)'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:20:27

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:43:12

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered empty.	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:20:27

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:43:12

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'Oral (ORAL)'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:20:27

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:43:12

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered empty.	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:20:27

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:43:12

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'un UNK 2017'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:20:27

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:43:12

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered '0'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:20:27

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:43:12

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'Yes (Y)'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:20:27

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:43:12

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

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered empty.	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:20:27

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:43:12

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
User entered 'No (N)'	Norma Barrientos (b) (4)	29 Aug 2020 23:20:27

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:43:12

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	29 Aug 2020 23:20:27

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:43:12

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	29 Aug 2020 23:20:27

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:43:12

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Aug 2020 23:20:27

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:43:12

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 01:55:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 01:55:45
Data point term sent to Coder	System	01 Oct 2020 01:54:09
Coding entries removed.	Crystal Mata (b) (4) (b) (4)	01 Oct 2020 01:53:47
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 12:45:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 12:45:47
Data point term sent to Coder	System	25 Sep 2020 12:45:19
Coding entries removed.	Norma Barrientos (b) (4) (b) (4)	25 Sep 2020 12:44:56
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Aug 2020 23:22:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Aug 2020 23:22:48
Data point term sent to Coder	System	29 Aug 2020 23:21:50
User entered 'Metformin'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:21:13

PRODUCTION RELEASE (v12.003
EAB) (1725)

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:43:12

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User closed query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 03:12:00
Query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' answered with 'not a prophylaxis criteria' (Site from DM).	maggie Tono (b) (4) (b) (4)	03 Nov 2020 21:00:50
User entered 'No (N)' reason for change: Data Entry Error	maggie Tono (b) (4) (b) (4)	03 Nov 2020 21:00:33
User opened query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 01:17:05
User entered 'Yes (Y)'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:21:13

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:43:12

Indication

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User closed query 'Per DM CLR RQ: Thank you for your response, however, the MH nor the AE eCRFs have been updated. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 06:01:13
Query 'Per DM CLR RQ: Thank you for your response, however, the MH nor the AE eCRFs have been updated. Please update accordingly.' answered with 'UPDATED MH ECRFS TO INCLUDE DIABETES TYPE 2, PER SOURCE.' (Site from DM).	Crystal Mata (b) (4) (b) (4)	01 Oct 2020 01:54:09
User entered 'DIABETES TYPE 2' reason for change: Data Entry Error	Crystal Mata (b) (4) (b) (4)	01 Oct 2020 01:53:47
User opened query 'Per DM CLR RQ: Thank you for your response, however, the MH nor the AE eCRFs have been updated. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 15:46:44
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).		28 Sep 2020 15:46:44
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' answered with 'updated ' (Site from DM).	Norma Barrientos (b) (4) (b) (4)	25 Sep 2020 12:45:11
User entered 'DIABETES Type II' reason for change: Data Entry Error	Norma Barrientos (b) (4) (b) (4)	25 Sep 2020 12:44:56
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 12:38:43
User entered 'Diabetes'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:21:13

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:43:12

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered '500'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:21:13

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:43:12

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'mg (mg)'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:21:13

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:43:12

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered empty.	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:21:13

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 15:43:12

Frequency

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'once daily (QD)'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:21:13

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:43:12

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered empty.	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:21:13

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:43:12

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'Oral (ORAL)'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:21:13

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:43:12

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered empty.	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:21:13

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:43:12

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'un UNK 2019'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:21:13

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:43:12

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered '0'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:21:13

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:43:12

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'Yes (Y)'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:21:13

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:43:12

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

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered empty.	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:21:13

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:43:12

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'No (N)'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:21:13

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:43:12

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	29 Aug 2020 23:21:13

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:43:12

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	29 Aug 2020 23:21:13

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:43:12

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Aug 2020 23:21:13

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:43:12

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
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)	29 Aug 2020 23:22:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Aug 2020 23:22:48
Data point term sent to Coder	System	29 Aug 2020 23:21:49
User entered 'Lisinopril'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:21:46

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:43:12

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'Yes (Y)'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:21:46

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:43:12

Indication

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'Hypertension'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:21:46

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:43:12

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered '10'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:21:46

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:43:12

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'mg (mg)'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:21:46

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:43:12

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered empty.	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:21:46

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:43:12

Frequency

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'once daily (QD)'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:21:46

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered empty.	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:21:46

FDA-CBER-2022-1614-0416179

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:43:12

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'Oral (ORAL)'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:21:46

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:43:12

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered empty.	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:21:46

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:43:12

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'un UNK 2015'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:21:46

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:43:12

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered '0'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:21:46

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:43:12

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'Yes (Y)'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:21:46

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:43:12

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

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered empty.	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:21:46

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:43:12

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'No (N)'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:21:46

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:43:12

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	29 Aug 2020 23:21:46

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:43:12

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	29 Aug 2020 23:21:46

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:43:12

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Aug 2020 23:21:46

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:43:12

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Aug 2020 23:23:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Aug 2020 23:23:48
Data point term sent to Coder	System	29 Aug 2020 23:22:51
User entered 'Oxycodone'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:22:35

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:43:12

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'Yes (Y)'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:22:35

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:43:12

Indication

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
User closed query 'Per DM CLR RQ: Thank you for your response, however, the MH nor the AE eCRFs have been updated for this indication. Please update accordingly' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Oct 2020 06:01:57
Query 'Per DM CLR RQ: Thank you for your response, however, the MH nor the AE eCRFs have been updated for this indication. Please update accordingly' answered with 'UPDATED MH ECRFS TO INCLUDE CHRONIC PAIN, PER SOURCE.' (Site from DM).	Crystal Mata (b) (4) (b) (4)	01 Oct 2020 01:55:39
User opened query 'Per DM CLR RQ: Thank you for your response, however, the MH nor the AE eCRFs have been updated for this indication. Please update accordingly' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 15:48:02
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).		28 Sep 2020 15:48:02
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' answered with 'updated ' (Site from DM).	Norma Barrientos (b) (4) (b) (4)	25 Sep 2020 12:47:34
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 12:37:59
User entered 'Chronic Pain'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:22:35

FDA-CBER-2022-1614-0416192

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:43:12

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered '5'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:22:35

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:43:12

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'mg (mg)'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:22:35

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:43:12

If dose unit is Other, specify

Audit	User		Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)		07 Apr 2021 14:37:48
User entered empty.	Norma Barrientos (b) (4) (b) (4)		29 Aug 2020 23:22:35

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:43:12

Frequency

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'as needed (PRN)'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:22:35

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:43:12

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered empty.	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:22:35

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:43:12

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'Oral (ORAL)'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:22:35

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:43:12

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered empty.	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:22:35

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:43:12

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'un UNK 2018'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:22:35

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:43:12

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered '0'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:22:35

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:43:12

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'Yes (Y)'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:22:35

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:43:12

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

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered empty.	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:22:35

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:43:12

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'No (N)'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:22:35

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:43:12

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	29 Aug 2020 23:22:35

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:43:12

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	29 Aug 2020 23:22:35

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:43:12

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered empty.	System	29 Aug 2020 23:22:35

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:43:12

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: COXIBS, PRODUCT: CELECOXIB, PRODUCTSYNONYM: CELEBREX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 12:49:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 12:49:48
Data point term sent to Coder	System	25 Sep 2020 12:48:20
Coding entries removed.	Norma Barrientos (b) (4) (b) (4)	25 Sep 2020 12:48:12
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: COXIBS, PRODUCT: CELECOXIB, PRODUCTSYNONYM: CELEBREX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Aug 2020 23:24:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Aug 2020 23:24:48
Data point term sent to Coder	System	29 Aug 2020 23:23:51
User entered 'Celebrex'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:23:42

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:43:12

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User closed query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 03:12:30
Query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' answered with 'not a prophylaxis criteria' (Site from DM).	maggie Tono (b) (4) (b) (4)	03 Nov 2020 21:01:44
User entered 'No (N)' reason for change: Data Entry Error	maggie Tono (b) (4) (b) (4)	03 Nov 2020 21:01:13
User opened query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 01:15:51
User entered 'Yes (Y)'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:23:42

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:43:12

Indication

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User closed query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis) and the location. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 15:48:21
Query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis) and the location. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'updated ' (Site from DM).	Norma Barrientos (b) (4) (b) (4)	25 Sep 2020 12:48:52
User entered 'osteoARTHRITIS' reason for change: Data Entry Error	Norma Barrientos (b) (4) (b) (4)	25 Sep 2020 12:48:12
User opened query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis) and the location. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 12:37:25
User entered 'Arthritis'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:23:42

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US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:43:12

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered '100'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:23:42

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:43:12

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'mg (mg)'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:23:42

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:43:12

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
User entered empty.	Norma Barrientos (b) (4)	29 Aug 2020 23:23:42

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:43:12

Frequency

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'twice daily (BID)'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:23:42

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:43:12

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered empty.	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:23:42

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:43:12

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'Oral (ORAL)'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:23:42

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:43:12

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered empty.	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:23:42

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:43:12

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'un UNK 2010'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:23:42

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:43:12

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered '0'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:23:42

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:43:12

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'Yes (Y)'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:23:42

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:43:12

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

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered empty.	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:23:42

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:43:12

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'No (N)'	Norma Barrientos (b) (4) (b) (4)	29 Aug 2020 23:23:42

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:43:12

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '2'	System	29 Aug 2020 23:23:42

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:43:12

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	29 Aug 2020 23:23:42

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:43:12

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Aug 2020 23:23:42

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:43:12

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:30:04
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 16:13:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 16:13:29
Data point term sent to Coder	System	23 Nov 2020 17:22:58
User entered 'flu shot'	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:22:40

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:43:12

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:30:04
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'Yes (Y)'	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:22:40

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:43:12

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:30:04
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'flu prevention'	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:22:40

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:43:12

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:30:04
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered '0.5'	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:22:40

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:43:12

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:30:04
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'mL (mL)'	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:22:40

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:43:12

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:30:04
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered empty.	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:22:40

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:43:12

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:30:04
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'once (ONCE)'	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:22:40

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:43:12

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:30:04
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered empty.	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:22:40

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:43:12

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:30:04
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'Intramuscular (INTRAMUSCULAR)'	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:22:40

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:43:12

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:30:04
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered empty.	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:22:40

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:43:12

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:30:04
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered '16 Oct 2020'	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:22:40

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:43:12

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:30:04
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered '0'	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:22:40

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:43:12

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:30:04
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'No (N)'	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:22:40

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:30:04
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered '16 Oct 2020'	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:22:40

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:43:12

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:30:04
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'No (N)'	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:22:40

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:43:12

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:30:04
User entered empty.	System	23 Nov 2020 17:22:40

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:43:12

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:30:04
User entered empty.	System	23 Nov 2020 17:22:40

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:43:12

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:30:04
User entered empty.	System	23 Nov 2020 17:22:40

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:43:12

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 19:28:42
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: VITAMIN K ANTAGONISTS, PRODUCT: WARFARIN SODIUM, PRODUCTSYNONYM: COUMADIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 16:13:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 16:13:34
Data point term sent to Coder	System	23 Nov 2020 17:36:22
User entered 'coumadin'	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:35:31

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:43:12

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 19:28:43
User entered 'No (N)'	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:35:31

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:43:12

Indication

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 19:28:46
User entered 'treatment of pulmonary embolism and deep vein thrombosis'	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:35:31

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:43:12

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User closed query 'Per DM CLR: Please review and remove 'ADJUSTABLE DOSING' from the dose field and add unit of measurement for this medication to the dose field. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 20:32:51
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 19:28:48
Query 'Per DM CLR: Please review and remove 'ADJUSTABLE DOSING' from the dose field and add unit of measurement for this medication to the dose field. Update Con Med eCRF as appropriate.' answered with 'updated' (Site from DM).	Yvonne De Los Reyes (b) (4)	03 Apr 2021 16:41:56
User entered '7.5' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	03 Apr 2021 16:37:23
User opened query 'Per DM CLR: Please review and remove 'ADJUSTABLE DOSING' from the dose field and add unit of measurement for this medication to the dose field. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 07:56:33
User entered 'adjustable dosing'	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:35:31

FDA-CBER-2022-1614-0416247

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:43:12

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 19:28:51
User entered 'mg (mg)' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	03 Apr 2021 16:37:23
User entered 'Other (OTHER)' reason for change: Data Entry Error	maggie Tono (b) (4) (b) (4)	31 Mar 2021 01:32:15
User entered 'mg (mg)'	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:35:31

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:43:12

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 19:28:53
User entered empty; reason for change Data Entry Error	Yvonne De Los Reyes (b) (4)	03 Apr 2021 16:37:23
User entered 'ADJUSTABLE DOSING' reason for change: Data Entry Error	maggie Tono (b) (4) (b) (4)	31 Mar 2021 01:32:15
User entered empty.	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:35:31

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:43:12

Frequency

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 19:28:56
User entered 'once daily (QD)'	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:35:31

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:43:12

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 19:28:58
User entered empty.	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:35:31

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:43:12

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 19:29:00
User entered 'Oral (ORAL)'	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:35:31

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:43:12

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 19:29:02
User entered empty.	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:35:31

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:43:12

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 19:29:05
User entered '3 Nov 2020'	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:35:31

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:43:12

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 19:29:06
User entered '0'	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:35:31

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:43:12

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 19:29:08
User entered 'Yes (Y)'	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:35:31

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:43:12

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

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 19:29:11
User entered empty.	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:35:31

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:43:12

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 19:29:12
User entered 'No (N)'	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:35:31

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:43:12

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	23 Nov 2020 17:35:31

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:43:12

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	23 Nov 2020 17:35:31

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:43:12

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Nov 2020 17:35:31

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:43:12

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:30:06
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 19:29:36
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: HEPARIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 06:04:15
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 06:04:15
Data point term sent to Coder	System	23 Nov 2020 17:46:32
User entered 'heparin'	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:45:33

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:43:12

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:30:06
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 19:29:37
User entered 'No (N)'	Saysamone Banks (b) (4)	23 Nov 2020 17:45:33

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:43:12

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:30:06
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 19:29:39
User entered 'treatment of pulmonary embolism and deep vein thrombosis'	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:45:33

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:43:12

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:30:06
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 19:29:41
User entered 'unknown'	Saysamone Banks (b) (4)	23 Nov 2020 17:45:33

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:43:12

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:30:06
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 19:29:42
User entered 'Other (OTHER)'	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:45:33

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:43:12

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:30:06
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 19:29:44
User entered 'unknown'	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:45:33

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:43:12

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:30:06
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 19:29:47
User closed query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).		30 Nov 2020 04:30:13
Query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' answered with 'patient only received medication once within a 24 hour time period' (Site from System).	Saysamone Banks (b) (4) (b) (4)	24 Nov 2020 21:38:30
User opened query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	23 Nov 2020 17:45:33
User entered 'once (ONCE)'	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:45:33

FDA-CBER-2022-1614-0416268

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:43:12

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:30:06
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 19:29:48
User entered empty.	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:45:33

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:43:12

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:30:06
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 19:29:50
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:45:33

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:43:12

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:30:06
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 19:29:52
User entered empty.	Saysamone Banks (b) (4)	23 Nov 2020 17:45:33

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:43:12

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:30:06
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 19:29:55
User entered '2 Nov 2020'	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:45:33

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:43:12

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:30:06
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 19:29:56
User entered '0'	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:45:33

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:43:12

Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:30:06
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 19:29:58
User entered 'No (N)'	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:45:33

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:43:12

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:30:06
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 19:30:00
User entered '3 Nov 2020'	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:45:33

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:43:12

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:30:06
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 19:30:01
User entered 'No (N)'	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:45:33

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:43:12

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:30:06
User entered empty.	System	23 Nov 2020 17:45:33

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:43:12

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:30:06
User entered empty.	System	23 Nov 2020 17:45:33

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:43:12

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 01:30:06
User entered empty.	System	23 Nov 2020 17:45:33

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:43:12

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
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)	03 Apr 2021 17:55:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Apr 2021 17:55:39
Data point term sent to Coder	System	03 Apr 2021 17:55:14
User entered 'Pantoprazole'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:55:00
DataPoint activated with code reason code Data required.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:54:21
DataPoint inactivated with code reason code Data not required.	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:45:57

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:43:12

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Apr 2021 17:55:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Apr 2021 17:55:06
User entered 'No (N)' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:55:06
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Apr 2021 17:55:00
User entered empty.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:55:00
DataPoint activated with code reason code Data required.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:54:21
DataPoint inactivated with code reason code Data not required.	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:45:57

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:43:12

Indication

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'Gastroesophageal reflux disease'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:55:00
DataPoint activated with code reason code Data required.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:54:21
DataPoint inactivated with code reason code Data not required.	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:45:57

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:43:12

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered '40'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:55:00
DataPoint activated with code reason code Data required.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:54:21
DataPoint inactivated with code reason code Data not required.	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:45:57

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:43:12

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'mg (mg)'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:55:00
DataPoint activated with code reason code Data required.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:54:21
DataPoint inactivated with code reason code Data not required.	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:45:57

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:43:12

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered empty.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:55:00
DataPoint activated with code reason code Data required.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:54:21
DataPoint inactivated with code reason code Data not required.	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:45:57

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:43:12

Frequency

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'twice daily (BID)'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:55:00
DataPoint activated with code reason code Data required.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:54:21
DataPoint inactivated with code reason code Data not required.	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:45:57

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:43:12

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered empty.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:55:00
DataPoint activated with code reason code Data required.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:54:21
DataPoint inactivated with code reason code Data not required.	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:45:57

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:43:12

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'Oral (ORAL)'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:55:00
DataPoint activated with code reason code Data required.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:54:21
DataPoint inactivated with code reason code Data not required.	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:45:57

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:43:12

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered empty.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:55:00
DataPoint activated with code reason code Data required.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:54:21
DataPoint inactivated with code reason code Data not required.	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:45:57

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:43:12

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'un UNK 2018'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:55:00
DataPoint activated with code reason code Data required.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:54:21
DataPoint inactivated with code reason code Data not required.	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:45:57

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:43:12

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered '0'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:55:00
DataPoint activated with code reason code Data required.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:54:21
DataPoint inactivated with code reason code Data not required.	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:45:57

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:43:12

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:55:00
DataPoint activated with code reason code Data required.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:54:21
DataPoint inactivated with code reason code Data not required.	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:45:57

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:43:12

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

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered empty.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:55:00
DataPoint activated with code reason code Data required.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:54:21
DataPoint inactivated with code reason code Data not required.	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:45:57

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:43:12

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:55:00
DataPoint activated with code reason code Data required.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:54:21
DataPoint inactivated with code reason code Data not required.	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:45:57

FDA-CBER-2022-1614-0416294

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:43:12

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '2'	System	03 Apr 2021 17:55:00
DataPoint activated with code reason code Data required.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:54:21
DataPoint inactivated with code reason code Data not required.	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:45:57

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:43:12

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	03 Apr 2021 17:55:00
DataPoint activated with code reason code Data required.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:54:21
DataPoint inactivated with code reason code Data not required.	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:45:57

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:43:12

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Apr 2021 17:55:00
DataPoint activated with code reason code Data required.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:54:21
DataPoint inactivated with code reason code Data not required.	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:45:57

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:43:12

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: PREGABALIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 04:04:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 04:04:39
Data point term sent to Coder	System	03 Apr 2021 17:56:15
User entered 'pregabalin'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:55:54

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:43:12

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:55:54

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:43:12

Indication

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'peripheral neuropathy/chronic pain'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:55:54

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:43:12

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered '75'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:55:54

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:43:12

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'mg (mg)'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:55:54

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:43:12

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered empty.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:55:54

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:43:12

Frequency

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'three times daily (TID)'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:55:54

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:43:12

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered empty.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:55:54

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:43:12

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'Oral (ORAL)'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:55:54

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:43:12

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered empty.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:55:54

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:43:12

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'un UNK 2019'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:55:54

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:43:12

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered '0'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:55:54

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:43:12

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:55:54

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:43:12

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

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered empty.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:55:54

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:43:12

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:55:54

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:43:12

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '3'	System	03 Apr 2021 17:55:54

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:43:12

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	03 Apr 2021 17:55:54

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:43:12

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Apr 2021 17:55:54

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:43:12

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: AZASPIRODECANEDIONE DERIVATIVES, PRODUCT: BUSPIRONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Apr 2021 17:58:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Apr 2021 17:58:41
Data point term sent to Coder	System	03 Apr 2021 17:57:15
User entered 'Buspirone'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:56:24

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:43:12

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:56:24

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:43:12

Indication

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'Anxiety'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:56:24

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:43:12

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered '5'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:56:24

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:43:12

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'mg (mg)'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:56:24

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:43:12

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered empty.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:56:24

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:43:12

Frequency

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'as needed (PRN)'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:56:24

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 15:43:12

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered empty.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:56:24

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:43:12

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'Oral (ORAL)'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:56:24

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:43:12

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
User entered empty.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:56:24

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:43:12

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'un UNK 2018'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:56:24

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:43:12

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered '0'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:56:24

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:43:12

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:56:24

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:43:12

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

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered empty.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:56:24

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:43:12

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:56:24

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:43:12

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	03 Apr 2021 17:56:24

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:43:12

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	03 Apr 2021 17:56:24

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:43:12

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered empty.	System	03 Apr 2021 17:56:24

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:43:12

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
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)	03 Apr 2021 17:58:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Apr 2021 17:58:42
Data point term sent to Coder	System	03 Apr 2021 17:57:15
User entered 'Ferrous sulfate'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:56:59

FDA-CBER-2022-1614-0416334

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:43:12

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:56:59

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:43:12

Indication

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'anemia'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:56:59

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:43:12

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered '325'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:56:59

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:43:12

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'mg (mg)'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:56:59

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:43:12

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered empty.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:56:59

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:43:12

Frequency

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'once daily (QD)'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:56:59

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:43:12

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered empty.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:56:59

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:43:12

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'Oral (ORAL)'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:56:59

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:43:12

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered empty.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:56:59

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'un UNK 2019'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:56:59

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:43:12

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered '0'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:56:59

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:43:12

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:56:59

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:43:12

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

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered empty.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:56:59

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:43:12

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:56:59

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:43:12

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	03 Apr 2021 17:56:59

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:43:12

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	03 Apr 2021 17:56:59

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:43:12

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Apr 2021 17:56:59

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:43:12

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: DIAZEPINES, OXAZEPINES, THIAZEPINES AND OXEPINES, PRODUCT: QUETIAPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Apr 2021 17:59:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Apr 2021 17:59:32
Data point term sent to Coder	System	03 Apr 2021 17:58:16
User entered 'Quetiapine'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:57:38

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:43:12

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:57:38

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'post traumatic stress disorder'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:57:38

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:43:12

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered '25'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:57:38

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:43:12

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'mg (mg)'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:57:38

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:43:12

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
	(b) (4)	
User entered empty.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:57:38

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:43:12

Frequency

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'three times daily (TID)'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:57:38

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:43:12

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered empty.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:57:38

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:43:12

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
	(b) (4)	
User entered 'Oral (ORAL)'	Yvonne De Los Reyes	03 Apr 2021 17:57:38
	(b) (4)	

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:43:12

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered empty.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:57:38

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:43:12

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'un UNK 2018'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:57:38

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:43:12

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered '0'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:57:38

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:43:12

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:57:38

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:43:12

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

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered empty.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:57:38

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:43:12

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:57:38

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:43:12

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '3'	System	03 Apr 2021 17:57:38

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:43:12

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	03 Apr 2021 17:57:38

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:43:12

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Apr 2021 17:57:38

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:43:12

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: OTHER ANTIPSYCHOTICS, PRODUCT: VALPROATE SEMISODIUM, PRODUCTSYNONYM: DIVALPROEX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 09:44:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 09:44:58
Data point term sent to Coder	System	03 Apr 2021 17:59:16
User entered 'Divalproex'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:58:19

Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:58:19

FDA-CBER-2022-1614-0416371

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:43:12

Indication

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'post traumatic stress disorder'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:58:19

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:43:12

Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered '250'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:58:19

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:43:12

Dose unit

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'mg (mg)'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:58:19

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:43:12

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
User entered empty.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:58:19

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:43:12

Frequency

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'once daily (QD)'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:58:19

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:43:12

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered empty.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:58:19

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:43:12

Route of administration

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'Oral (ORAL)'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:58:19

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:43:12

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered empty.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:58:19

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:43:12

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'un UNK 2018'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:58:19

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:43:12

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered '0'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:58:19

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:43:12

Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:58:19

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:43:12

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

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered empty.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:58:19

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:43:12

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 17:58:19

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:43:12

Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	03 Apr 2021 17:58:19

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:43:12

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	03 Apr 2021 17:58:19

US3192486

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:43:12

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Apr 2021 17:58:19

US3192486

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:43:12

Were any concomitant procedures performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:15:36
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User closed query 'Per source please review and enter 'stent placement pancreas' as applicable. Thanks' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 03:12:24
User closed query 'Per source subject went in for an endoscopy. Please review and add procedure as applicable. ' (Site from CRA).		07 Apr 2021 03:12:12
User closed query 'Per source GI bleed was due to 'colonoscopy'. Please review and add procedure as applicable. Thanks' (Site from CRA).		07 Apr 2021 03:11:57
Query 'Per source please review and enter 'stent placement pancreas' as applicable. Thanks' answered with 'updated ' (Site from CRA).	Yvonne De Los Reyes (b) (4)	03 Apr 2021 16:42:44
Query 'Per source subject went in for an endoscopy. Please review and add procedure as applicable. ' answered with 'updated ' (Site from CRA).	Yvonne De Los Reyes (b) (4)	03 Apr 2021 16:42:40
Query 'Per source GI bleed was due to 'colonoscopy'. Please review and add procedure as applicable. Thanks' answered with 'updated ' (Site from CRA).	Yvonne De Los Reyes (b) (4)	03 Apr 2021 16:42:16
User opened query 'Per source please review and enter 'stent placement pancreas' as applicable. Thanks' (Site from CRA).	(b) (4), (b) (6)	20 Jan 2021 19:41:52
User opened query 'Per source subject went in for an endoscopy. Please review and add procedure as applicable. ' (Site from CRA).		20 Jan 2021 19:37:48
User opened query 'Per source GI bleed was due to 'colonoscopy'. Please review and add procedure as applicable. Thanks' (Site from CRA).		20 Jan 2021 19:18:33
DataPoint Verified.		20 Jan 2021 19:17:17
User entered 'Yes (Y)' reason for change: New Information	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:46:46
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	12 Sep 2020 15:58:54

US3192486

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:43:12

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 19:36:18
User entered '3 Nov 2020'	Saysamone Banks (b) (4)	23 Nov 2020 17:49:39
	(b) (4)	

US3192486

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:43:12

Procedure/Surgery

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 19:36:18
User entered 'blood transfusion'	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:49:39

US3192486

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:43:12

Indication

Audit	User	Time (GMT)
User closed query 'Per CDM: Please review and confirm if this procedure is related to AE, if yes please select Indication as 'Adverse Event'. Thank you. ' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 11:44:52
User signature succeeded.	John McGettigan (b) (4) (b) (4)	13 Apr 2021 15:09:23
User closed query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	System	12 Apr 2021 18:28:45
Query 'Per CDM: Please review and confirm if this procedure is related to AE, if yes please select Indication as 'Adverse Event'. Thank you. ' answered with 'updated' (Site from DM).	maggie Tono (b) (4) (b) (4)	12 Apr 2021 18:28:09
User opened query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	System	12 Apr 2021 18:27:42
DataPoint Un-verified.	maggie Tono (b) (4) (b) (4)	12 Apr 2021 18:27:42
Signature has been broken.	maggie Tono (b) (4) (b) (4)	12 Apr 2021 18:27:42
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	maggie Tono (b) (4) (b) (4)	12 Apr 2021 18:27:42
User opened query 'Per CDM: Please review and confirm if this procedure is related to AE, if yes please select Indication as 'Adverse Event'. Thank you. ' (Site from DM).	(b) (4), (b) (6)	10 Apr 2021 13:52:29
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 19:36:18
User closed query 'Per DM CLR: Indication = Adverse Event, however, the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification.' (Site from DM).		02 Apr 2021 02:40:16
Query 'Per DM CLR: Indication = Adverse Event, however, the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification.' answered with 'updated' (Site from DM).	maggie Tono (b) (4) (b) (4)	31 Mar 2021 15:41:00

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US3192486

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:43:12

Indication

Audit	User	Time (GMT)
User entered 'Other (OTHER)' reason for change: Data Entry Error	maggie Tono (b) (4) (b) (4)	31 Mar 2021 15:40:53
User opened query 'Per DM CLR: Indication = Adverse Event, however, the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 13:27:21
User entered 'Adverse Event (AE)'	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:49:39

US3192486

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:43:12

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	13 Apr 2021 15:09:23
DataPoint Un-verified.	maggie Tono (b) (4) (b) (4)	12 Apr 2021 18:28:45
Signature has been broken.	maggie Tono (b) (4) (b) (4)	12 Apr 2021 18:28:45
User entered empty; reason for change Data Entry Error	maggie Tono (b) (4) (b) (4)	12 Apr 2021 18:28:45
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 19:36:18
User entered 'Concomitant Procedure' reason for change: Data Entry Error	maggie Tono (b) (4) (b) (4)	31 Mar 2021 15:40:53
User entered empty.	Saysamone Banks (b) (4) (b) (4)	23 Nov 2020 17:49:39

US3192486

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:43:12

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:13:55
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 19:36:36
User entered '02 Nov 2020'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 16:43:12

US3192486

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:43:12

Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:13:55
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 19:36:36
User entered 'Colonoscopy'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 16:43:12

US3192486

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:43:12

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:13:55
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 19:36:36
User entered 'Diagnostic (DIAGNOSTIC)'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 16:43:12

US3192486

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:43:12

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:13:55
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 19:36:36
User entered empty.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 16:43:12

US3192486

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:43:12

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:14:10
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 03:10:03
User closed query 'Per con. procedure log date of procedure was changed to 02Nov2020, but per records received from VA hospital, date of procedure is 02Nov2020. Please confirm which date is correct. Thanks' (Site from CRA).		07 Apr 2021 03:09:02
Query 'Per con. procedure log date of procedure was changed to 02Nov2020, but per records received from VA hospital, date of procedure is 02Nov2020. Please confirm which date is correct. Thanks' answered with 'correct date is 02Nov2020' (Site from CRA).	Yvonne De Los Reyes (b) (4)	03 Apr 2021 19:43:14
User entered '02 Nov 2020' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	03 Apr 2021 19:43:02
User opened query 'Per con. procedure log date of procedure was changed to 02Nov2020, but per records received from VA hospital, date of procedure is 02Nov2020. Please confirm which date is correct. Thanks' (Site from CRA).	(b) (4), (b) (6)	03 Apr 2021 19:35:59
User entered '13 Nov 2020'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 16:43:26

US3192486

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:43:12

Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:14:10
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 19:36:03
User entered 'Endoscopy'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 16:43:26

US3192486

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:43:12

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:14:10
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 19:36:05
User entered 'Diagnostic (DIAGNOSTIC)'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 16:43:26

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US3192486

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:43:12

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:14:10
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Apr 2021 19:36:06
User entered empty.	Yvonne De Los Reyes (b) (4)	03 Apr 2021 16:43:26

US3192486

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 15:43:12

Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:14:23
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered '02 Nov 2020'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 19:43:49

US3192486

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 15:43:12

Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:14:23
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'pancreatic stent placement'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 19:43:49

US3192486

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 15:43:12

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:14:23
User closed query 'Per CDM: Please review and confirm if this procedure is related to AE, if yes please select Indication as 'Adverse Event'. Thank you.' (Site from DM).		19 Apr 2021 11:45:07
User signature succeeded.	John McGettigan (b) (4) (b) (4)	13 Apr 2021 15:09:23
Query 'Per CDM: Please review and confirm if this procedure is related to AE, if yes please select Indication as 'Adverse Event'. Thank you.' answered with 'updated' (Site from DM).	maggie Tono (b) (4) (b) (4)	12 Apr 2021 21:42:54
Signature has been broken.	maggie Tono (b) (4) (b) (4)	12 Apr 2021 21:42:38
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	maggie Tono (b) (4) (b) (4)	12 Apr 2021 21:42:38
User opened query 'Per CDM: Please review and confirm if this procedure is related to AE, if yes please select Indication as 'Adverse Event'. Thank you.' (Site from DM).	(b) (4), (b) (6)	10 Apr 2021 13:54:37
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'Other (OTHER)'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 19:43:49

US3192486

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 15:43:12

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:14:23
User signature succeeded.	John McGettigan (b) (4) (b) (4)	13 Apr 2021 15:09:23
Signature has been broken.	maggie Tono (b) (4) (b) (4)	12 Apr 2021 21:42:38
User entered empty; reason for change Data Entry Error	maggie Tono (b) (4) (b) (4)	12 Apr 2021 21:42:38
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered 'procedure'	Yvonne De Los Reyes (b) (4)	03 Apr 2021 19:43:49

US3192486
Folder: SAE USA-US097-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:43:12
SAEID

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:36:42
Reviewed for Safety.		23 Nov 2020 20:58:17
User entered 'USA-US097-2020-MRNA-1273-P301000006'	System	23 Nov 2020 20:57:28

US3192486
Folder: SAE USA-US097-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:43:12
Serious

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:36:42
Reviewed for Safety.		23 Nov 2020 20:58:17
User entered 'Yes (Y)'	System	23 Nov 2020 20:57:28

US3192486
Folder: SAE USA-US097-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:43:12
Death

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:36:42
Reviewed for Safety.		23 Nov 2020 20:58:17
User entered 'No (N)'	System	23 Nov 2020 20:57:28

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:36:42
Reviewed for Safety.		23 Nov 2020 20:58:17
User entered 'No (N)'	System	23 Nov 2020 20:57:28

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US3192486
Folder: SAE USA-US097-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:43:12
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:36:42
Reviewed for Safety.		23 Nov 2020 20:58:17
User entered 'Yes (Y)'	System	23 Nov 2020 20:57:28

US3192486
Folder: SAE USA-US097-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:43:12
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:36:42
Reviewed for Safety.		23 Nov 2020 20:58:17
User entered 'No (N)'	System	23 Nov 2020 20:57:28

US3192486

Folder: SAE USA-US097-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:12

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:36:42
Reviewed for Safety.		23 Nov 2020 20:58:17
User entered 'No (N)'	System	23 Nov 2020 20:57:28

US3192486
Folder: SAE USA-US097-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:43:12
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:36:42
Reviewed for Safety.		23 Nov 2020 20:58:17
User entered 'No (N)'	System	23 Nov 2020 20:57:28

US3192486
Folder: SAE USA-US097-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:43:12
Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:36:42
Reviewed for Safety.		23 Nov 2020 20:58:17
User entered 'John'	System	23 Nov 2020 20:57:28

US3192486
Folder: SAE USA-US097-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:43:12

Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:36:42
Reviewed for Safety.		23 Nov 2020 20:58:17
User entered 'McGettigan'	System	23 Nov 2020 20:57:28

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:36:42
Reviewed for Safety.		23 Nov 2020 20:58:17
User entered '5390 E. Erickson Drive'	System	23 Nov 2020 20:57:28

US3192486
Folder: SAE USA-US097-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:43:12
Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:36:42
Reviewed for Safety.		23 Nov 2020 20:58:17
User entered 'Tucson'	System	23 Nov 2020 20:57:28

US3192486
Folder: SAE USA-US097-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:43:12

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:36:42
Reviewed for Safety.		23 Nov 2020 20:58:17
User entered 'AZ'	System	23 Nov 2020 20:57:28

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:36:42
Reviewed for Safety.		23 Nov 2020 20:58:17
User entered '85712'	System	23 Nov 2020 20:57:28

FDA-CBER-2022-1614-0416419

US3192486
Folder: SAE USA-US097-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:43:12

Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:36:42
Reviewed for Safety.		28 Dec 2020 13:57:49
User entered 'US'	System	23 Nov 2020 20:58:32

US3192486

Folder: SAE USA-US097-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:12

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '5'	System	30 Apr 2021 15:49:41
User entered '4'	System	05 Apr 2021 13:35:09
User entered '3'	System	26 Mar 2021 14:12:01
User entered '2'	System	28 Dec 2020 13:58:02
User entered '1'	System	23 Nov 2020 20:58:32

US3192486
Folder: SAE USA-US097-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:43:12
SAEID

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:36:42
Reviewed for Safety.		23 Nov 2020 20:58:17
User entered 'USA-US097-2020-MRNA-1273-P301000006'	System	23 Nov 2020 20:57:28

FDA-CBER-2022-1614-0416422

US3192486
Folder: SAE USA-US097-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:43:12
Serious

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:36:42
Reviewed for Safety.		23 Nov 2020 20:58:17
User entered 'Yes (Y)'	System	23 Nov 2020 20:57:28

US3192486
Folder: SAE USA-US097-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:43:12
Death

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:36:42
Reviewed for Safety.		23 Nov 2020 20:58:17
User entered 'No (N)'	System	23 Nov 2020 20:57:28

US3192486
Folder: SAE USA-US097-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:43:12
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:36:42
Reviewed for Safety.		23 Nov 2020 20:58:17
User entered 'No (N)'	System	23 Nov 2020 20:57:28

US3192486
Folder: SAE USA-US097-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:43:12
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:36:42
Reviewed for Safety.		23 Nov 2020 20:58:17
User entered 'Yes (Y)'	System	23 Nov 2020 20:57:28

US3192486
Folder: SAE USA-US097-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:43:12
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:36:42
Reviewed for Safety.		23 Nov 2020 20:58:17
User entered 'No (N)'	System	23 Nov 2020 20:57:28

US3192486
Folder: SAE USA-US097-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:43:12

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:36:42
Reviewed for Safety.		23 Nov 2020 20:58:17
User entered 'No (N)'	System	23 Nov 2020 20:57:28

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:36:42
Reviewed for Safety.		23 Nov 2020 20:58:17
User entered 'No (N)'	System	23 Nov 2020 20:57:28

FDA-CBER-2022-1614-0416429

US3192486
Folder: SAE USA-US097-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:43:12
Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:36:42
Reviewed for Safety.		23 Nov 2020 20:58:17
User entered 'John'	System	23 Nov 2020 20:57:28

US3192486
Folder: SAE USA-US097-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:43:12
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:36:42
Reviewed for Safety.		23 Nov 2020 20:58:17
User entered 'McGettigan'	System	23 Nov 2020 20:57:28

US3192486
Folder: SAE USA-US097-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:43:12
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:36:42
Reviewed for Safety.		23 Nov 2020 20:58:17
User entered '5390 E. Erickson Drive'	System	23 Nov 2020 20:57:28

US3192486
Folder: SAE USA-US097-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:43:12
Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:36:42
Reviewed for Safety.		23 Nov 2020 20:58:17
User entered 'Tucson'	System	23 Nov 2020 20:57:28

FDA-CBER-2022-1614-0416433

US3192486
Folder: SAE USA-US097-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:43:12
Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:36:42
Reviewed for Safety.		23 Nov 2020 20:58:17
User entered 'AZ'	System	23 Nov 2020 20:57:28

US3192486
Folder: SAE USA-US097-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:43:12
Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:36:42
Reviewed for Safety.		23 Nov 2020 20:58:17
User entered '85712'	System	23 Nov 2020 20:57:28

US3192486
Folder: SAE USA-US097-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:43:12

Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:36:42
Reviewed for Safety.		28 Dec 2020 13:57:49
User entered 'US'	System	23 Nov 2020 20:58:32

US3192486

Folder: SAE USA-US097-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:12

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '5'	System	30 Apr 2021 15:49:41
User entered '4'	System	05 Apr 2021 13:35:09
User entered '3'	System	26 Mar 2021 14:12:01
User entered '2'	System	28 Dec 2020 13:58:02
User entered '1'	System	23 Nov 2020 20:58:32

US3192486

Folder: SAE USA-US097-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:43:12

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:36:42
User entered '23/Nov/2020 20:58'	System	23 Nov 2020 20:58:32

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.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:36:42
Reviewed for Safety.		28 Dec 2020 13:57:49
User entered '1'		23 Nov 2020 20:58:32

US3192486
Folder: SAE USA-US097-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:43:12
SAEID

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:36:42
Reviewed for Safety.		23 Nov 2020 20:58:17
User entered 'USA-US097-2020-MRNA-1273-P301000006'	System	23 Nov 2020 20:57:28

US3192486
Folder: SAE USA-US097-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:43:12
Serious

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:36:42
Reviewed for Safety.		23 Nov 2020 20:58:17
User entered 'Yes (Y)'	System	23 Nov 2020 20:57:28

US3192486
Folder: SAE USA-US097-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:43:12
Death

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:36:42
Reviewed for Safety.		23 Nov 2020 20:58:17
User entered 'No (N)'	System	23 Nov 2020 20:57:28

US3192486
Folder: SAE USA-US097-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:43:12
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:36:42
Reviewed for Safety.		23 Nov 2020 20:58:17
User entered 'No (N)'	System	23 Nov 2020 20:57:28

US3192486

Folder: SAE USA-US097-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:12

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:36:42
Reviewed for Safety.		23 Nov 2020 20:58:17
User entered 'Yes (Y)'	System	23 Nov 2020 20:57:28

US3192486

Folder: SAE USA-US097-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:12

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:36:42
Reviewed for Safety.		23 Nov 2020 20:58:17
User entered 'No (N)'	System	23 Nov 2020 20:57:28

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:36:42
Reviewed for Safety.		23 Nov 2020 20:58:17
User entered 'No (N)'	System	23 Nov 2020 20:57:28

US3192486
Folder: SAE USA-US097-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:43:12
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:36:42
Reviewed for Safety.		23 Nov 2020 20:58:17
User entered 'No (N)'	System	23 Nov 2020 20:57:28

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:36:42
Reviewed for Safety.		23 Nov 2020 20:58:17
User entered 'John'	System	23 Nov 2020 20:57:28

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:36:42
Reviewed for Safety.		23 Nov 2020 20:58:17
User entered 'McGettigan'	System	23 Nov 2020 20:57:28

US3192486
Folder: SAE USA-US097-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:43:12
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:36:42
Reviewed for Safety.		23 Nov 2020 20:58:17
User entered '5390 E. Erickson Drive'	System	23 Nov 2020 20:57:28

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:36:42
Reviewed for Safety.		23 Nov 2020 20:58:17
User entered 'Tucson'	System	23 Nov 2020 20:57:28

FDA-CBER-2022-1614-0416451

US3192486
Folder: SAE USA-US097-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:43:12
Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:36:42
Reviewed for Safety.		23 Nov 2020 20:58:17
User entered 'AZ'	System	23 Nov 2020 20:57:28

US3192486
Folder: SAE USA-US097-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:43:12
Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:36:42
Reviewed for Safety.		23 Nov 2020 20:58:17
User entered '85712'	System	23 Nov 2020 20:57:28

US3192486
Folder: SAE USA-US097-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:43:12

Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:36:42
Reviewed for Safety.		28 Dec 2020 13:57:49
User entered 'US'	System	23 Nov 2020 20:58:32

US3192486

Folder: SAE USA-US097-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:12

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '5'	System	30 Apr 2021 15:49:41
User entered '4'	System	05 Apr 2021 13:35:09
User entered '3'	System	26 Mar 2021 14:12:01
User entered '2'	System	28 Dec 2020 13:58:02
User entered '1'	System	23 Nov 2020 20:58:32

US3192486

Folder: SAE USA-US097-2020-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:43:12

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:36:42
User entered '28/Dec/2020 13:58'	System	28 Dec 2020 13:58:02

US3192486

Folder: SAE USA-US097-2020-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:43:12

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.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 14:11:50
DataPoint Verified.		20 Jan 2021 19:36:42
User entered '1'		28 Dec 2020 13:58:02

US3192486
Folder: SAE USA-US097-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:43:12

SAEID

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:36:42
Reviewed for Safety.		23 Nov 2020 20:58:17
User entered 'USA-US097-2020-MRNA-1273-P301000006'	System	23 Nov 2020 20:57:28

US3192486

Folder: SAE USA-US097-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:12

Serious

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:36:42
Reviewed for Safety.		23 Nov 2020 20:58:17
User entered 'Yes (Y)'	System	23 Nov 2020 20:57:28

US3192486
Folder: SAE USA-US097-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:43:12
Death

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:36:42
Reviewed for Safety.		23 Nov 2020 20:58:17
User entered 'No (N)'	System	23 Nov 2020 20:57:28

US3192486
Folder: SAE USA-US097-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:43:12

Life threatening

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:36:42
Reviewed for Safety.		23 Nov 2020 20:58:17
User entered 'No (N)'	System	23 Nov 2020 20:57:28

US3192486
Folder: SAE USA-US097-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:43:12

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:36:42
Reviewed for Safety.		23 Nov 2020 20:58:17
User entered 'Yes (Y)'	System	23 Nov 2020 20:57:28

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:36:42
Reviewed for Safety.		23 Nov 2020 20:58:17
User entered 'No (N)'	System	23 Nov 2020 20:57:28

US3192486
Folder: SAE USA-US097-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:43:12
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:36:42
Reviewed for Safety.		23 Nov 2020 20:58:17
User entered 'No (N)'	System	23 Nov 2020 20:57:28

US3192486

Folder: SAE USA-US097-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:12

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:36:42
Reviewed for Safety.		23 Nov 2020 20:58:17
User entered 'No (N)'	System	23 Nov 2020 20:57:28

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:36:42
Reviewed for Safety.		23 Nov 2020 20:58:17
User entered 'John'	System	23 Nov 2020 20:57:28

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:36:42
Reviewed for Safety.		23 Nov 2020 20:58:17
User entered 'McGettigan'	System	23 Nov 2020 20:57:28

US3192486
Folder: SAE USA-US097-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:43:12
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:36:42
Reviewed for Safety.		23 Nov 2020 20:58:17
User entered '5390 E. Erickson Drive'	System	23 Nov 2020 20:57:28

US3192486
Folder: SAE USA-US097-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:43:12

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:36:42
Reviewed for Safety.		23 Nov 2020 20:58:17
User entered 'Tucson'	System	23 Nov 2020 20:57:28

US3192486
Folder: SAE USA-US097-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:43:12
Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:36:42
Reviewed for Safety.		23 Nov 2020 20:58:17
User entered 'AZ'	System	23 Nov 2020 20:57:28

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:36:42
Reviewed for Safety.		23 Nov 2020 20:58:17
User entered '85712'	System	23 Nov 2020 20:57:28

FDA-CBER-2022-1614-0416471

Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:36:42
Reviewed for Safety.		28 Dec 2020 13:57:49
User entered 'US'	System	23 Nov 2020 20:58:32

US3192486

Folder: SAE USA-US097-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:12

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '5'	System	30 Apr 2021 15:49:41
User entered '4'	System	05 Apr 2021 13:35:09
User entered '3'	System	26 Mar 2021 14:12:01
User entered '2'	System	28 Dec 2020 13:58:02
User entered '1'	System	23 Nov 2020 20:58:32

US3192486

Folder: SAE USA-US097-2020-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:43:12

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Apr 2021 19:17:47
User entered '26/Mar/2021 09:11'	System	26 Mar 2021 14:12:01

US3192486

Folder: SAE USA-US097-2020-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:43:12

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.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:33:29
DataPoint Verified.		03 Apr 2021 19:17:47
User entered '1'		26 Mar 2021 14:12:01

US3192486
Folder: SAE USA-US097-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:43:12
SAEID

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:36:42
Reviewed for Safety.		23 Nov 2020 20:58:17
User entered 'USA-US097-2020-MRNA-1273-P301000006'	System	23 Nov 2020 20:57:28

US3192486
Folder: SAE USA-US097-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:43:12
Serious

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:36:42
Reviewed for Safety.		23 Nov 2020 20:58:17
User entered 'Yes (Y)'	System	23 Nov 2020 20:57:28

US3192486
Folder: SAE USA-US097-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:43:12
Death

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:36:42
Reviewed for Safety.		23 Nov 2020 20:58:17
User entered 'No (N)'	System	23 Nov 2020 20:57:28

US3192486
Folder: SAE USA-US097-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:43:12
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:36:42
Reviewed for Safety.		23 Nov 2020 20:58:17
User entered 'No (N)'	System	23 Nov 2020 20:57:28

FDA-CBER-2022-1614-0416479

US3192486
Folder: SAE USA-US097-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:43:12

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:36:42
Reviewed for Safety.		23 Nov 2020 20:58:17
User entered 'Yes (Y)'	System	23 Nov 2020 20:57:28

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:36:42
Reviewed for Safety.		23 Nov 2020 20:58:17
User entered 'No (N)'	System	23 Nov 2020 20:57:28

FDA-CBER-2022-1614-0416481

US3192486

Folder: SAE USA-US097-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:12

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:36:42
Reviewed for Safety.		23 Nov 2020 20:58:17
User entered 'No (N)'	System	23 Nov 2020 20:57:28

US3192486
Folder: SAE USA-US097-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:43:12
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:36:42
Reviewed for Safety.		23 Nov 2020 20:58:17
User entered 'No (N)'	System	23 Nov 2020 20:57:28

US3192486
Folder: SAE USA-US097-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:43:12

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:36:42
Reviewed for Safety.		23 Nov 2020 20:58:17
User entered 'John'	System	23 Nov 2020 20:57:28

US3192486
Folder: SAE USA-US097-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:43:12

Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:36:42
Reviewed for Safety.		23 Nov 2020 20:58:17
User entered 'McGettigan'	System	23 Nov 2020 20:57:28

US3192486
Folder: SAE USA-US097-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:43:12
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:36:42
Reviewed for Safety.		23 Nov 2020 20:58:17
User entered '5390 E. Erickson Drive'	System	23 Nov 2020 20:57:28

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:36:42
Reviewed for Safety.		23 Nov 2020 20:58:17
User entered 'Tucson'	System	23 Nov 2020 20:57:28

FDA-CBER-2022-1614-0416487

US3192486
Folder: SAE USA-US097-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:43:12
Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:36:42
Reviewed for Safety.		23 Nov 2020 20:58:17
User entered 'AZ'	System	23 Nov 2020 20:57:28

US3192486
Folder: SAE USA-US097-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:43:12
Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:36:42
Reviewed for Safety.		23 Nov 2020 20:58:17
User entered '85712'	System	23 Nov 2020 20:57:28

US3192486
Folder: SAE USA-US097-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:43:12

Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:36:42
Reviewed for Safety.		28 Dec 2020 13:57:49
User entered 'US'	System	23 Nov 2020 20:58:32

US3192486

Folder: SAE USA-US097-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:12

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '5'	System	30 Apr 2021 15:49:41
User entered '4'	System	05 Apr 2021 13:35:09
User entered '3'	System	26 Mar 2021 14:12:01
User entered '2'	System	28 Dec 2020 13:58:02
User entered '1'	System	23 Nov 2020 20:58:32

US3192486

Folder: SAE USA-US097-2020-MRNA-1273-P301000006

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:43:12

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
User entered '05/Apr/2021 13:34'	System	05 Apr 2021 13:35:09

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.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
User entered '1'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:35:09

US3192486
Folder: SAE USA-US097-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:43:12
SAEID

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:36:42
Reviewed for Safety.		23 Nov 2020 20:58:17
User entered 'USA-US097-2020-MRNA-1273-P301000006'	System	23 Nov 2020 20:57:28

US3192486
Folder: SAE USA-US097-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:43:12
Serious

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:36:42
Reviewed for Safety.		23 Nov 2020 20:58:17
User entered 'Yes (Y)'	System	23 Nov 2020 20:57:28

US3192486
Folder: SAE USA-US097-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:43:12
Death

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:36:42
Reviewed for Safety.		23 Nov 2020 20:58:17
User entered 'No (N)'	System	23 Nov 2020 20:57:28

US3192486
Folder: SAE USA-US097-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:43:12
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:36:42
Reviewed for Safety.		23 Nov 2020 20:58:17
User entered 'No (N)'	System	23 Nov 2020 20:57:28

US3192486
Folder: SAE USA-US097-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:43:12

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:36:42
Reviewed for Safety.		23 Nov 2020 20:58:17
User entered 'Yes (Y)'	System	23 Nov 2020 20:57:28

US3192486
Folder: SAE USA-US097-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:43:12
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:36:42
Reviewed for Safety.		23 Nov 2020 20:58:17
User entered 'No (N)'	System	23 Nov 2020 20:57:28

US3192486

Folder: SAE USA-US097-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:12

Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:36:42
Reviewed for Safety.		23 Nov 2020 20:58:17
User entered 'No (N)'	System	23 Nov 2020 20:57:28

Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:36:42
Reviewed for Safety.		23 Nov 2020 20:58:17
User entered 'No (N)'	System	23 Nov 2020 20:57:28

FDA-CBER-2022-1614-0416501

US3192486
Folder: SAE USA-US097-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:43:12

Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:36:42
Reviewed for Safety.		23 Nov 2020 20:58:17
User entered 'John'	System	23 Nov 2020 20:57:28

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:36:42
Reviewed for Safety.		23 Nov 2020 20:58:17
User entered 'McGettigan'	System	23 Nov 2020 20:57:28

FDA-CBER-2022-1614-0416503

US3192486
Folder: SAE USA-US097-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:43:12

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:36:42
Reviewed for Safety.		23 Nov 2020 20:58:17
User entered '5390 E. Erickson Drive'	System	23 Nov 2020 20:57:28

US3192486
Folder: SAE USA-US097-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:43:12

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:36:42
Reviewed for Safety.		23 Nov 2020 20:58:17
User entered 'Tucson'	System	23 Nov 2020 20:57:28

US3192486
Folder: SAE USA-US097-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:43:12
Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:36:42
Reviewed for Safety.		23 Nov 2020 20:58:17
User entered 'AZ'	System	23 Nov 2020 20:57:28

US3192486
Folder: SAE USA-US097-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:43:12
Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 19:36:42
Reviewed for Safety.		23 Nov 2020 20:58:17
User entered '85712'	System	23 Nov 2020 20:57:28

Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	07 Apr 2021 14:37:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Jan 2021 19:36:42
Reviewed for Safety.		28 Dec 2020 13:57:49
User entered 'US'	System	23 Nov 2020 20:58:32

US3192486

Folder: SAE USA-US097-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:12

E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '5'	System	30 Apr 2021 15:49:41
User entered '4'	System	05 Apr 2021 13:35:09
User entered '3'	System	26 Mar 2021 14:12:01
User entered '2'	System	28 Dec 2020 13:58:02
User entered '1'	System	23 Nov 2020 20:58:32

US3192486

Folder: SAE USA-US097-2020-MRNA-1273-P301000006

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:43:12

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 19:41:54
User entered '30/Apr/2021 11:49'	System	30 Apr 2021 15:49:41

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.

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4) (b) (4)	30 Apr 2021 19:41:54
User entered '1'	(b) (4), (b) (6)	30 Apr 2021 15:49:41

FDA-CBER-2022-1614-0416511